KANGAROO-MOTHER CARE -

A SYSTEMATIC REVIEW OF THE LITERATURE

AND

A PROTOCOL FOR A RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Kangaroo-Mother Care (KMC) is a relatively new intervention for the management of low birth weight babies, consisting of skin-to-skin contact with breastfeeding. This minithesis consists of three main parts:

- a literature review of KMC and related topics,
- a systematic review of trials on KMC,
- a protocol for a randomised controlled trial on birth KMC.

The literature review outlines the origin and development of KMC. Relevant biological and anthropological articles are summarised to provide a full background, as well as the recent history of modern neonatal care. Epidemiological and public health aspects relating to skin-to-skin contact, breastfeeding generally, breastfeeding of prematures, and feeding methods are reviewed. Research on KMC and the current status of KMC is described. Finally proposed rationales and hypotheses for KMC are summarised.

The systematic review analyses 29 trials incorporating any control group, of these 14 articles were randomised controlled trials, the remainder being interrupted time series or historical controls. Only 6 trials were appraised as unlikely to be biased. All trials on birth KMC were done on fullterm infants. No trials on fullterm or premature infants showed any adverse effects of KMC. Comparisons of articles was difficult due to the variety of contexts and parameters described. A framework of the essential context and management parameters which are required to properly interpret controlled trials and management programmes for KMC is presented.

A single study with an historical control suggests perinatal mortality can be improved with KMC practised continuously from birth. A formal randomised controlled trial is required before policy recommendations on this can be made. A fully prepared protocol with this objective concludes this thesis. Its primary hypothesis is that skin-to-skin contact from birth is superior to current conventional methods of care. It would in fact suffice to show that KMC is safe, and as good as the incubator for caring for the newborn. The study will require four nurse researchers to conduct continuous monitoring of cardiorespiratory functions for 6 hours post-birth on 100 mother-infant dyads, randomly assigned to KMC or conventional method of care. A detailed study design with data collection forms is provided, at a stage just prior to submission for ethics committee approval and funding application.

(362 words)

KEY WORDS

Kangaroo mother care, skin-to-skin-care, neonatology, framework, breastfeeding, physiological parameters, management, systematic review, randomised controlled trial, protocol.

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DEFINITIONS

Kangaroo-Mother Care	The placing of newborn infants, whether premature or not, naked on their mother's nude chests for maternal-infant skin-to-skin contact, with the encouragement of exclusive breastfeeding. Early discharge can be part of KMC, or possible with KMC
Kangaroo Care	Term generally used in the USA to denote mother-infant skin-to-skin contact (SSC), with less regard for breastfeeding or early discharge.
Conventional Method of Care	The standard method of care of newborns, generally referring to premature infants, differs from hospital to hospital. The term is generally used in contrast to KMC as intervention.
Kangaroo position	Maternal-infant skin-to-skin contact
Kangaroo nutrition	In developing world context referring to exclusive or near exclusive breastfeeding of prematures.
Kangaroo discharge	The planned early discharge of stabilised prematures in kangaroo position and with kangaroo nutrition, regardless of weight and gestational age.
Framework	A matrix or system of categorising an intervention to allow standard categories of otherwise continuous phenomena.
Sucking	Term reserved for feeding mechanism of infant from bottle.
Suckling	The feeding (ingestion) mechanism the infant uses on mother's breast.
Premature	Term used to signify infants born before 37 weeks of gestational age (36 completed weeks or less).

ABBREVIATIONS

AGA	Appropriate for gestational age
BBA	Born Before Arrival
BFHI	Baby Friendly Hospital Initiative
BM	Breast milk
C/S	Caesarean Section
CCT	Controlled Clinical Trial
CMC	Conventional Method of Care
ELBW	Extreme Low Birthweight (< 1000g)
GA	Gestational age
IMR	Infant Mortality Rate
KC	Kangaroo Care
KMC	Kangaroo-Mother Care
KMI	Kangaroo Mother Intervention
LBW	Low Birthweight (< 2500g)
LGA	Large for gestational age
MOU	Midwife Obstetric Unit
NICU	Neonatal Intensive Care Unit
PCA	Post conceptional age
PMNS	Peninsula Maternity and Neonatal Service
PHC	Primary Health Care
PNMR	Perinatal Mortality Rate
RCT	Randomised Controlled Trial
SGA	Small for gestational age
SSC	Skin-to-skin contact
UNICEF	United Nations Children's Emergency Fund
VLBW	Very Low Birthweight (< 1500g)
WHO	World Health Organisation

SECTION ONE REVIEW OF THE LITERATURE

Origins and introduction

Kangaroo-mother care (KMC) was brought to the attention of the English speaking medical literature by Whitelaw and Sleath (1985). This followed media attention and support by UNICEF for "kangaroo babies", which claimed "intriguing and incredible" survival, unparalleled in the medical literature. Dr Rey and Dr Martinez had started a programme in 1978 in Bogota, in response to a severely overcrowded, under-equipped and understaffed neonatal unit, with cross infections common and poor survival of low birthweight babies. In the new programme, babies that survived the initial stabilisation period, were placed skin to skin on their mothers, given help with breastfeeding and provided supplements if required, and then discharged home. It was these babies that had showed the impressive survival figures, large numbers of babies still died before being started on KMC. Though Whitelaw and Sleath summarise by saying "Colombia has nothing to teach developed countries about improving survival", they were intrigued enough to conclude "but (Colombia) may yet help us to heal some of the psychological problems incurred by modern neonatal care".

This review addresses some biological and anthropological background to the newborn period and breastfeeding. The development of neonatal care over the last one hundred years, particularly as regards premature care is described, as well as the current global status of health provision for premature infants. Some principles of the Primary Health Care approach is highlighted, with respect to public health aspects of two ongoing and inter-related controversies: the option of incubator care versus skin-to-skin care, and the option of breastfeeding versus formula feeding. The findings on KMC of researchers and experiences of implementation from the literature is reviewed. The review concludes with an overview of the various hypotheses and rationales that have been described to explain the effects of KMC.

The literature review is followed by a systematic review of the literature. Of all available articles on KMC, all articles comparing a KMC group with any control group have been selected. These articles have been critically appraised for various kinds of bias. The firm conclusions that can be

drawn from the literature are summarised. Some recommendations for practice and further research are presented.

The final section is a protocol for a randomised controlled trial, which would study KMC initiated at birth compared to conventional care. The primary hypothesis is that "skin-to-skin contact from birth is superior to conventional methods of care". This is broken down into seven measurable hypotheses, with the primary end-point being six hours, the hypothesised stabilisation period. The intention is to submit this protocol for funding and conduct it as described.

Biology and anthropology

From a biological perspective, *Homo sapiens* is a mammal. Defining for mammals is that they breastfeed, the word being derived from the Latin *mamma*, meaning breast. (Fowler 1969). In recent years, biologists have extensively researched the newborn period and breastfeeding in mammals ranging from rats to primates. Their findings have been summarised for the benefit of the medical world in a symposium report (Kjellmer and Winberg 1994). During pregnancy hormones (estrogen, progesterone and prolactin mainly) are responsible for priming the mother, and also for triggering parturition (Rosenblatt 1994). After birth however, events are determined not by hormones nor by the mother, but by the behaviour of the newborn in stimulating the mother, which leads to the initiation and the maintenance of breastfeeding (Rosenblatt 1994). The process does of course require the mother, there is a "set of mutual complex sensory stimulations in mother and child" (Kjellmer and Winberg 1994). These phases are based on "central programmes embodied in the brain stem and the old mammalian brain" (Kjellmer and Winberg 1994), and are "remarkably similar across species" (Keverne and Kendrick 1994). A common feature in all species studied, is that the initiative in establishing breastfeeding lies with the newborn, not the mother. The particular expression of the newborn stimulating the mother does vary from species to species, but certain features are always present. Olfactory cues are "critical to activate suckling" (Alberts 1994; Numan 1994). The newborn has all the capabilities required to initiate suckling, if it is in the correct or appropriate environment (Alberts 1994). Suckling causes morphological changes in the brain of the mother, with subsequent beneficial

physiological changes (Modney and Hatton, 1994). For all mammals, this breastfeeding, or suckling, "is a remarkably fragile and transient behaviour" (Alberts 1994). The process is started by the newborn immediately after birth, and is "easily disturbed by any intervention" (Christensson et al 1992). Unless suckling is started soon after birth, and unless suckling is allowed to continue, the newborn loses its ability to suckle (Alberts 1994).

Apart from feeding, protection and warmth are two other universal needs of mammalian newborn (Kjellmer and Winberg 1994). Mammals have three patterns of newborn heat generation (Christensson et al 1992). In "immature" there is no infant capacity to make heat; "altricial" have low or moderate capacity at birth; and "precocial" have fully developed heat generation capacity. All immature and altricial mammals use their own bodies as a heat source (Christensson et al 1992). Many have "nesting" behaviour, but primates generally use the "cling and carry" method, where the mother is the mobile nest and heat source in one. Precocial ungulates are described as "leading-following" (Rosenblatt 1994).

The basic needs of the newborn require an environment that provides protection, warmth and the opportunity to initiate suckling. For all mammals studied, separation of the newborn from the mother leads to problems and pathology (Rosenblum and Andrews 1994). This pathology is most obvious in the newborn, but can also lead to problems for the mother (Modney and Hatton, 1994). Separation causes a well-preserved sequence of responses in all species, with immediate "separation distress cries" (Alberts 1994), and a sequence of "protest followed by despair behaviour", the two being regarded as a "single integrated psychophysiological response" (Hofer 1994). Concomitant with this is a massive rise in stress hormones, which leads subsequently to a state of lowered metabolism, with slowed heart rate and lowered temperature (Hofer 1994).

Hofer (1994) in fact describes the above initially from human infants, starting with deprivation studies after the Second World War, which led to research in rhesus monkeys, and thence to other mammals. The biologists quoted above all provide evidence that there is an evolutionarily developed agenda for the newborn period, and "violations of this agenda can result in pathology (Kjellmer and Winberg 1994). **The primary "violation" described by the biologists is separation.** Quote from Alberts (1994): 'to the extent we place infants in environments which

differ from their evolutionary niches, there is increasing potential for malleable processes to become redirected ... (to the) evolutionary unexpected, and that some new patterns might constitute pathology". "Early separation can produce major shifts in susceptibility to stress-induced pathology" (Hofer 1994). Rosenblum and Andrews (1994) discussing mother infant adaptation conclude: "enforced separation may result in altered neurodevelopment and a diminished capacity of the infant to cope with a changing world, and may leave a residue of vulnerability to stress that may be carried throughout the infant's life". In summarising these findings and looking to the human, the editors of the symposium write: "The origins of many behavioural deviations (child neglect, abuse, abnormal shyness, attention deficiencies, hyperactivity, colic, sleep disorders etc) are unknown - can some be traced back to violations of an innate agenda?" (Kjellmer and Winberg 1994).

Human biology and anthropology

McKenna et al (1993), reviewing the fossil record of Homo species, suggest that the conflicting evolutionary trend of bipedalism (which caused a narrower pelvis), and increasing brain size (which needed a broader pelvis) was resolved by the birth of exceedingly immature infants, with only 25% of final brain size (chimpanzee has 45%, other species more). The growth of the increased brain had to take place outside the womb. The argument is here that since this development is as (evolutionarily) old as we are *Homo sapiens*, so too the immaturity and the biological adaptations to cope with that. This immaturity requires greater provision of warmth and protection, or "sustained physical contact with a caregiver".

Confirmation of the human newborn's ability to initiate breastfeeding according to the biologists' research has been provided by Widstrom et al (1987). These authors were studying the effects of gastric suction in a randomised controlled trial, on healthy fullterm infants. Both groups were left on the mother's chest, skin-to-skin, for the first hour after birth. The study group had the routine gastric suction procedure performed, apart from that both groups were left undisturbed on the mothers' abdomens. Some adverse effects of gastric suction were found, and the conclusion of the study was that the practice should be discontinued. However, a chance finding was made on

the control group of ten normal un-drugged newborns. These all established breastfeeding spontaneously within one hour. Being a control group under close observation for behaviour, they were not to be interfered with by the mother or the staff. They all exhibited the same sequence of pre-feeding behaviour, consisting of sucking and rooting mouth movements, then hand to mouth movements, then reaching for the nipple, latching and suckling. Gastric suction disrupted and delayed this sequence, though all but one did suckle. They do not comment on it, but this pattern is exactly that described for all mammals species studied and described above, except that the time period appears to be longer. This may perhaps be due to the extreme immaturity of the human infant from the biological perspective.

Widstrom described healthy fullterm infants. Wahlberg, (1991, reporting the work of Persson), describes a "wheel" of steps whereby premature infants will breastfeed. From a biological perspective, these should be regarded as "premature immature" newborns. Nevertheless, the "innate agenda" (Alberts 1994) suggested to be in the brainstem, appears to be present in these. The wheel applies the concepts reported by the biologists, in terms on the correct environment, olfactory cues, and suckling behaviour. A key component is the environment or habitat, which here is skin-to-skin contact. With this method, infants of 28 gestational weeks of age are able to suckle, previously thought possible only for 36 week gestation infants (Anderson 1989a).

This environment, skin-to-skin contact, has been described by Christensson et al (1992) as "the maternal nest created by her chest and breast". In a careful study these authors compared one group receiving SSC with another group cared for in a bed during the first 90 minutes of life. The SSC group showed higher temperatures and more rapid metabolic adaptation. Though the brain may exhibit evolutionary immaturity at birth, in terms of thermogenesis, human newborns are altricial (Christensson et al 1992). Though some authors state that fullterm infants have a "full complement of thermoregulatory responses" (Mondlane et al 1989), others note that even in warm countries, hypothermia in the newborn period is common (Christensson et al 1992). For premature and small babies, heat generation is very inadequate, and hypothermia associated with significant mortality (Mondlane et al 1989).

The composition of human milk, with a low protein content, requires a high frequency of feeds. This also suggests that during evolution there was constant mother-infant contact for nursing (McKenna et al 1993). It is clear from the animal studies and the above, that all the vital requirements of the newborn, (the establishment of breastfeeding, protection and warmth) are dependent on being in the correct environment, which is in close physical contact with the mother. Returning briefly to the rats of Alberts (1994): the developing rat is described as passing through a **sequence of habitats** (e.g. uterus, mother's body, nest of siblings, the world), and for each habitat it is fully developed and equipped. Removed from its appropriate habitat, it is unable to behave as "programmed", and is at risk. In other words: breastfeeding, warming and protection behaviours are intricately and inseparably linked into one programme appropriate to the habitat, which for this stage of development is the mother's body. This statement might appear obvious until we examine how the human newborn is treated in the Western culture, see further below.

Recent studies of animal parent-infant separation show that major detrimental physiological adjustments, with "changes in the fundamental efficiency of systems", take place on separation (McKenna 1993). Human infants, being far more immature than the animals studied, should be expected to be even more vulnerable to such effects (McKenna 1993). Again, the physiological response to separation from the mother, (the appropriate habitat), appears to be remarkably similar in all mammals studied, including man, as described above (Hofer 1994). Anderson et al (1998, also Chang et al 1993) showed doubled cortisol levels at 6 hours postbirth in infants separated from their mothers after one hour, compared to those in contact, all other care being the same. Premature infants in incubators have been shown to have circulating glucocorticoids approaching neurotoxic levels, and only SSC was shown to be able to significantly lower these (Mooncey et al 1997).

McKenna et al (1993), reviewing infant sleep, state that all the evidence suggests that "infant-parent co-sleeping represents the species-wide pattern of sleep in which human infant physiology evolved". Co-sleeping provides heat for newborns and children in most non-Western cultures. There is evidence of this from the Middle East dating back many centuries: "Don't bother me, the door is already locked, and my children are with me in bed" (Gospel of Luke, chapter 11, verse 7). It appears our recent Western culture is unique in regarding the "solitary sleeping infant" as

the norm or normal, and this "may have adverse physiological or neurodevelopmental consequences" (McKenna et al 1993). The same article also suggests that the co-sleeping microenvironment provides a higher carbon dioxide content which may increase the respiratory drive of infants.

Some recent history

The first textbook of neonatology was written by the Frenchman Pierre Budin in 1907 (Klaus and Kennell, 1976). At that time there was high morbidity and mortality among hospitalised patients, and "germs" were identified as the main enemy. This led to strict isolation techniques, as it was believed that visitors were the source of infection. Both fullterm and premature infants were swiftly separated from their mothers, and nursed in isolation with as little contact as possible.

In this context Budin noted that though premature newborns were saved, they were often abandoned by their mothers. He attributed this to the early separation that hospital care forced on them. He designed the glass walled incubator, which allowed the mother to look at the baby even if isolated. He encouraged the mother both to help with the care of the baby, and to breastfeed, even if premature. With these changes, mothers remained attentive to their babies, and abandonment was very rare.

Martin Cooney, a pupil of Budin, applied the precepts he learned in Germany. As premature infants were not expected to live, they were given to Cooney, who raised them successfully in his "child hatchery". In 1896 he exhibited this at the Berlin Exposition, and the exhibit was a commercial success. These exhibits continued until 1940, and at the 1932 Chicago World Fair the child hatchery was the second most lucrative exhibit.

There was however one major precept of Budin which Cooney ignored: he separated the mother from baby and excluded her from the care of the infant. The only concession to mothers was free passes to the exhibits. Subsequently, on occasions he had great difficulty getting mothers to take their babies back when they reached five pounds. In the course of these exhibitions, Cooney

settled in the United States. Here maternity hospitals for fullterm babies followed his methods, and the exclusion of mothers became accepted practice. The first hospital centre for premature care (Sarah Morris, Chicago, 1923) also followed his principles, though here mothers were encouraged to produce milk at home and bring it to hospital. After the Second World War this method of care was almost universal. One of only two exceptions to this model of care was the premature unit in Baragwanath, South Africa, where mothers were directly involved in care of their own infants, with excellent survival (Klaus and Kennell 1976). From the late 1960's there has been a slow trend of allowing mothers into hospitals more and more, though the fear of "germs" remains, evident in barriers and no-touch policies.

After the Second World War a new period of "positive medical treatment of premature infants began" (Silverman 1992). This replaced the nurse driven "neutral care" of feeding, warming and isolating. The new period was characterised by an uncritical "let's try and see" approach. A number of therapies were tried and appeared to give good results, only to be found detrimental when re-examined some years later. The first example was in 1954 when a randomised clinical trial showed that high dose oxygen caused retinal damage: over 12 years thousands of infants had been blinded. In 1956 a RCT of the "positive pressure airlock", used widely for 6 years, showed decreased mortality in the untreated controls (Silverman 1992). Since the 1970's, RCT have generally been done before introducing innovations. There has also been an "explosion in diagnostic technology", a rapid technological advancement, which saw increased survival of lower gestational age infants. With this technology and new knowledge, care became "more mechanistic" (Silverman 1992).

In 1907, Budin wrote: "Unfortunately, a certain number of mothers abandon the babies whose needs they have not had to meet, and in whom they have lost all interest. The life of the little one has been saved, it is true, but at the cost of the mother" (Klaus and Kennell, 1976).

Klaus and Kennell (1976) made similar observations. They noted a high incidence of battered babies among those prematures that had been sent home doing well. They also noted "failure to thrive without organic cause", and saw that a very high proportion of such cases were prematures but also other infants who had been separated from their mothers at birth. They surmised that a

key factor for infant survival was the mother's attachment to the infant. They (and other workers, e.g. Brazelton) were able to show that there was a critical period in the first few minutes and hours after birth when this attachment process started. Mother-infant dyads denied this opportunity had completely different behaviours and attitudes. They recognised also the integral wholeness of the dyad: "it is misleading to look only at one member of the dyad in this complex interaction". Klaus and Kennell (1976) are credited with describing "bonding", and demonstrating the dramatic effects of early contact.

Their ideas were initially not accepted by the medical profession. Lamb (1982) laments the lack of scientific evidence for the positive effects of bonding, claiming that the results of 20 studies showed "no enduring effects on either mothers or infants". Klaus and Kennell (1983) defend the scientific validity and findings of the studies critiqued by Lamb, and find support from other trials.

In the last decade technological advancement has been such that infants of 24 weeks of gestational age and weights of 500g can survive, with a good quality of life in 85% of cases (Stjernqvist and Svenningsen 1995). Attitudes to parents' presence have also changed, they are encouraged to visit and take part in care (Stjernqvist 1993). From such contexts and experiences the concepts of bonding and attachment have been reconsidered (Stjernqvist 1993). "Bonding" is referred to as a critical time period at birth resulting in specific behaviours, and for the human this is regarded as less important. It is however valuable in contributing to "attachment" - which is seen as a more vital but prolonged reciprocal process taking up the first year of life.

The epidemiological perspective.

Though advanced technology can save the lives of premature infants, that technology is not affordable or accessible to the vast majority of the world's premature children. The State of the World's Children 1995 (Grant, 1995) and the World Development Report 1993 (World Bank, 1993) provide figures from which a calculation of the number of low birthweight babies born

worldwide can be made, as well as resources to care for them. (Low birth weight is defined as less than 2500g)

Table 1 Global distribution of premature infants and resources.

World Development Report (1993), figures for 1991	
(Population x Crude Birth Rate x Low Birthweight rate)	
Low Income countries	LBW babies
China	1,52 million
India	7,8 million
Rest	6,3 million
Total	15,6 million
Middle income countries	(no LBW rate provided)
High income countries	0,64 million
Comparing high income to low income countries,	
we find that the low income countries have	
96% of the prematures	(Grant 1995)
4.8% of the nurses	(Grant 1995)
1.8% of the doctors	(Grant 1995)
0.8% of the incubators	*(this author's guesstimate)*

The "positive medical treatment of prematures" referred to above (Silverman 1992), began in the 1940's in the developed countries, out of the growing awareness that low birthweight was the single largest contributor to neonatal mortality. This applies even more to the developing world currently. It is estimated that 65% of the global neonatal mortality rate is directly due to, or associated with, prematurity (Sanders 1985). This leads to a vicious cycle in survivors: effects of low birthweight continue into the fourth year, resulting in stunted children with decreased intellectual potential, and subsequently mothers who are short and at risk and conceive low birthweight babies themselves (Sanders 1985). The weakened mother and child are more susceptible to infections, which in turn exacerbate the nutritional status.

Global perspective on problem

Currently it is estimated that 5 million children under five years die annually (Grant 1995). Over half of those deaths are directly or indirectly due to or associated with prematurity. KMC presents a very real advance in terms of their potential survival, a 5 fold increase in survival for babies between 1000g and 1500g has been shown using KMC from birth (Bergman and Jurisoo, 1994). If the safety of KMC can unequivocally be established, WHO and UNICEF will formally endorse it. This has the potential for saving over one million lives per year, see box below.

Table 2 Potential impact of improved neonatal survival

World Development Report (1993), figures for 1991	
(Population x Crude Birth Rate x Low Birthweight rate)	
Low Income countries	LBW babies
China	1,52 million
India	7,8 million
Rest	6,3 million
Total	15,6 million
Middle income countries	(no LBW rate)
High income countries	0,64 million
Assume 20% are 1000 to 1499g	
Assume neonatal mortality rate (NMR) decreased from 90% to 50%	
Apply only to low income countries	
15,6 million x 20% x 90%	2,8 million
15,6 million x 20% x 50%	1,56 million
Potential lives saved	**1,24 million per year**

Public health aspects of skin-to-skin contact.

The management of prematurity is therefore a public health priority. Any measure that can significantly impact on the improved survival of prematures will directly impact mortality rates. Any measure that would provide improved health status for prematures would indirectly impact

mortality rates, in that associated causes will be diminished, and susceptibility to other diseases would be less.

The incubator has been regarded as necessary for the improved survival of prematures (Mondlane 1989). As is seen in the Table 1 above, there is an enormous maldistribution of resources between high and low income countries, both with regard to medical staff and to equipment such as incubators. Incubators are also technologically demanding in terms of operation, maintenance, upkeep and repairs. In conditions of poverty and lack of qualified staff, such technology is inappropriate, and may do more harm than good.

Appropriate technology is one of the basic principles of the Primary Health Care approach, which was codified in the Declaration of Alma Ata in 1978 (WHO, 1978). Though criticised subsequently, the Primary Health Care (PHC) approach remains fundamental to the success of any health programme in the developing world, if not the developed world. The PHC approach has been adopted in various forms by many governments worldwide. The PHC approach recognises that health is dependent on socio-economic development, but declares that socioeconomic development cannot take place without the health of people. The people therefore need to be directly involved in planning and implementation of health care. Available resources should be focussed on essential health needs as identified by the people themselves. Interventions should be based on "practical, scientifically sound and socially acceptable methods and technology, made universally accessible to people with their full participation, and at a cost they can afford now and in the future" (WHO 1978).

Considering appropriate technology, Mondlane et al (1989) enumerate a number of alternative approaches to the incubator that have been tried in developing countries, all having limited success. Working in Mozambique, the poorest country in the world as of 1991 (World Bank 1993), they described the use of skin-to-skin contact as originally described by Rey and Martinez (Whitelaw and Sleath 1985), and found it as good as, if not better than, the incubator for keeping premature infants warm. Davanzo (1993) writes "The choice of the K-M method (KMC) is obligatory ... in a context of lack" (of resources).

Public health aspects of breastfeeding.

Rey and Martinez also emphasised the importance of breastfeeding as part of their intervention of KMC. Whereas there has been little acceptance of skin-to-skin care in policy, breastfeeding has the full support of the WHO and UNICEF, and a public health programme in the form of the Baby-Friendly Hospital Initiative. This is sometimes referred to as the "10 steps", as there are ten directives that have to be implemented fully to be accorded Baby-Friendly status.

One of the slogans of the above Initiative is "Breast is Best". A detailed account of the benefits of breastfeeding is beyond the scope of this paper. Though formula may be designed to provide most of the nutritional requirements, it cannot provide the immunological and psychosocial benefits of breast milk and breastfeeding. Over 14 separate antibacterial factors and 8 antiviral factors have been shown to be active in breastmilk (Webber 1998). In Brazil non-breastfed infants had a 14 times greater risk of death from diarrhoea than those who breastfed exclusively (Victora et al 1987). It has been estimated that worldwide, 7 million infants are saved every year by breastfeeding, and a further 1,5 million could be saved through more effective promotion of it (MacIntyre et al, 1995). The economic benefits of breastfeeding are considerable, and have recently been highlighted in the 1998 World Breastfeeding Week (Greiner and Baumslag 1998).

Labbok and Krasovec (1990) have presented a "schema and framework" as an attempt to ensure precision and consistency in the definition of breastfeeding. They note that without consistent and precise definitions, data can be misinterpreted, and studies cannot be compared. This makes accurate conclusions impossible, and hampers the development of sound policy. In their paper they suggest a "schema" which divides breastfeeding into full, partial and token, with some subdivisions in each group. The "framework" then applies to each kind of breastfeeding, which should be described in terms of age of infant, frequency, duration, feeding intervals, use of devices, expression of milk, information on other feeds, and a frame for any other information that may be relevant in the particular circumstance. The authors stress that the framework provides a minimum of what should be described. This framework applies to a point in time; for the sequence of feeding it would need to be applied several times.

Breastfeeding and the premature

A subject which has received considerable attention over the last ten years is the subject of breastfeeding the premature infant. There is a growing body of literature on this, most of which has been summarised in a review by Schanler (1995). Having regarded nutritional aspects, gastrointestinal considerations, host defense considerations and developmental outcomes, he states "we question the use of human milk based on some specific nutritional inadequacies, but recommend its feeding for the profound effects it has on host defense and body structural function." He advises different milk delivery techniques (ensuring the fat reaches the baby), and the addition of nutritional components. "The emerging host-defense data warrant extraordinary efforts to provide nutritionally adequate milk to the high risk population of low birthweight infants" (Schanler 1995). In an even more detailed review, Steichen et al (1987) provide quantitative data on all then considered nutritional elements, noting inadequacy in protein, calcium and phosphorus, some trace elements, and possibly a number of vitamins, and later iron. They likewise emphasise the overriding advantages of breast milk, and give guidelines on supplementation and fortification. They also emphasise the benefits of using the baby's own mothers milk, which will have a more optimal protein composition and more active/current secretory antibodies. Pediatrics electronic pages, (September 1998; 102:e38), reports that for newborn infants below 1500 g "being human milk-fed decreased the odds of infection by 57%".

Meier & Brown (1996) review breastfeeding of preterm infants. In addition to the numerous benefits accruing to fullterm infants, particular benefits for preterm infants fed with human breastmilk include less necrotising enterocolitis, protection from infection, greater enteral feed tolerance, reduced risk of later allergy, improved retinal function, and enhanced neurocognitive development. Though there is such potential gain to be had, fewer preterm infants end up breastfeeding than fullterm infants.

Feeding method

Although what is fed to newborns has received much attention, how it is fed has been little studied. Breastmilk is generally delivered to the newborn by suckling. For prematures however it may need to be expressed, and can then be given (like formula) by nasogastric tube, by cup or

spoon, or by bottle. Suckling (as opposed to sucking) has been shown to induce positive effects on the newborn over and above the mere ingestion of nutrient (Alberts 1994). Neurogenic mechanisms normally induced by oral feeding are activated by suckling a pacifier, resulting in improved gastrointestinal motility (Widstrom et al 1988). Suckling induces calmness and energy conservation, and has been shown to be antinociceptive (Blass 1994).

Suckling and sucking have been shown to be myographically distinct, completely different muscles being involved (Alberts 1994). Whereas suckling (feeding from the breast) results in positive effects, sucking from a bottle has in recent years been shown to have potentially negative effects. Meier and Anderson (1987) compared successive bottle and breast feeds in 34 week prematures, and found consistent patterns. During bottle feeds, sucking occurred in bursts in which swallowing and breathing were not coordinated, and there was fairly rapid development of significant lowering of oxygen saturation, which was accompanied by bradycardia in many cases, in some infants so severe as to necessitate with-holding subsequent bottle feeds. On cessation of sucking, oxygen saturation returned to normal, but after ten minutes a post feed decline as severe as during sucking was noted. Breast feeds however showed a small but consistent cyclical variation about the baseline, the variation decreasing with maturity. Actual feeds were considerably longer, and after feeds a small rise in oxygen saturation was noted. Meier (1988) suggests that the "ability to breastfeed precedes ability to bottle feed for small preterm infants." Though these authors do not suggest it, clearly a feeding method that causes hypoxia and bradycardia is both destabilising and stressful for small prematures. Bosque et al (1987) report bradycardia associated with both bottle feeds and gavage feeds, but not with breastfeeding.

Though new research continues to find benefits of breastfeeding, and the medical and nursing professions generally agree that it is superior to the bottle and formula, breastfeeding is rare in many countries and still declining in others. Certain countries have however seen a dramatic change over the last years - for example in Sweden, breastfeeding rates have risen from lows around 20% in the 1970s to 70% in the 1990's (Hofvander and Hillervik 1995).

Research on Kangaroo-Mother Care

KMC was first described from Bogota (Whitelaw and Sleath 1985, see introduction). Bogota is situated at 2600m above sea level, and this is partly blamed for an increased low birthweight rate.

Following their visit to Bogota, Whitelaw and Sleath continued researching KMC (Whitelaw 1986, Whitelaw et al 1988, Whitelaw and Liestol, 1994). A commentary on a randomised controlled trial of 70 infants showed significantly improved lactation from a mere 36 minutes skin-to-skin contact per day, marked psychological advances, no increase in sepsis, adequate or improved oxygenation, and well controlled temperature (Whitelaw 1990).

Other visits to Bogota followed, many resulting in various forms of skin-to-skin care being established in various parts of the world. Gene Cranston Anderson visited Bogota the year after Whitelaw and Sleath (Anderson et al, 1986), and has popularised KMC in North America (Anderson 1989a; Anderson 1989b), and continues to research and promote its use, (Anderson 1991). Wahlberg visited with Anderson and has promoted KMC in Sweden and other European countries (Wahlberg 1986, Wahlberg 1993).

Up until 1991, only 4 randomised controlled trials had been reported on KMC (Anderson, 1991). Schmidt and Wittreich (1986) showed marked improvement in lactation with regard to numbers of mothers feeding, number of feeds per day, and total volume produced per day (640ml versus 400ml per day): findings supported by Tuomikoski-Koiranen (1988). The trial of Whitelaw et al (1988) is discussed above. Ludington et al (1991) measured minute to minute heart rates, respiratory rates, oxygenation and temperature, showing all to be within normal limits with KMC, and documenting a reduction in periodic breathing while on KMC.

Numerous trials have used repeated measures and historical controls, both less rigorous from a research point of view. Samples have generally been small, and the selection criteria very variable. Findings have however been fairly consistent. Basic physiological parameters are stable or improved, temperature is well controlled, and there is no increase in infections. Breastfeeding

is enhanced, in respect of mother's ability to feed, willingness to maintain feeding and volume of milk produced (Affonso et al, 1989).

De Leeuw et al (1991), and de Leeuw (1986) studied very small and nonstabilised infants, and found KMC to be safe, with a variety of minor physiological benefits, but significant benefits for mothers. Ludington (1991) has also studied energy conservation and behavioural state in infants on KMC compared to incubator care, showing significant benefits in both respects with KMC.

Uvnas-Moberg et al (1987) reviewed research on gastro-intestinal hormones in newborns. Sensory stimulation (such as skin-to-skin contact and non-nutritive sucking) has been shown to cause a vagally mediated release of gut hormones such as gastrin and cholecystokinin. Gastrin stimulates acid secretion, but in the newborn also stimulates growth of the gastric mucosa. Cholecystokinin stimulates secretion of pancreatic juices, but also growth of the pancreas itself. Vagal nerve activity also inhibits the release of somatostatin, which in large amounts inhibits effects of growth hormone and of all other 20 or so described gastrointestinal hormones. Stress on the other hand, rapidly raises levels of somatatostatin, with inhibition of gastro-intestinal motility and hormone secretion.

Benefits to mothers have been researched also. Anderson (1977), in research predating the Kangaroo programme in Bogota, describes the mother and her newborn as "mutual caregivers". The positive effects of SSC on the fetal gastrointestinal function and hormonal profile is seen also in the mother (Uvnas-Moberg et al 1987). Affonso et al (1993) describe profound effects on mothers' search for meaning, sense of mastery and self-esteem following skin to skin caregiving. Feelings of shame and guilt, common but often ignored in mothers of low birthweight babies, can be overcome, with KMC allowing a feeling of "completing the pregnancy" (Affonso et al 1986).

A number of articles have shown significant cost savings, and late benefits of KMC. For example, a trial in Ecuador (Sloan et al, 1994) was terminated early due to a significantly lower incidence of severe morbidity at 6 months in favour of KMC babies, despite these babies coming from poorer socio-economic circumstances than the control group. This trial also showed marked savings in hospital cost of care.

Bergman and Jurisoo (1994) describe KMC implemented from 1988 in the absence of incubators, allowing for skin-to-skin care from birth, and practised continuously. Total survival of babies between 1000g and 1500 g improved from 10% to 50% in a historical control. These survivors generally stabilised within one or two days. All were discharged on exclusive breastfeeding. Kambarami et al (1998) showed improved survival in a Third world tertiary hospital setting, with available incubators.

Previous major reviews

The first significant review on SSC was by **Anderson (1991)**. This review provides a table of all then known research articles on SSC, arranged in order of decreasing rigour. Four categories of KMC are described, late (stabilised), intermediate (still on oxygen etc), early (for newborns stable at birth), and very early (first minute). Generally trials reported are small, and there is no critical appraisal of their quality. It is noted however that results of all trials "have yielded rather consistent findings that support the safety and value of kangaroo care". Babies were warm enough, had good oxygenation and no increase in infection. They cried less and slept better, went home sooner and were crying less at 6 months of age. Their mothers had thermal synchrony with their babies, were more inclined to breastfeed, produced more milk and fed for longer. They were more confident in caring for their babies, and keener to go home early.

In this review there are only four randomised controlled trials, nine trials employing repeated measures, and four with historical and retrospective controls. Thirteen descriptive studies are listed.

Two important reviews appeared in 1996. Ludington-Hoe and Swinth (1996) provide a review of research confined to SSC, relating findings to this. Charpak et al (1996) review "Kangaroo Mother Intervention", by which they mean a three part intervention of skin-to-skin contact, breastfeeding, and early discharge.

Ludington-Hoe and Swinth (1996) reviewed "kangaroo care (skin-to-skin holding)" with regard to the five dimensions of neurobehavioural development: autonomic, motor, state, attention/interaction, and selfregulation. In each dimension, the goal is "an organised infant who responds without disruption in physiologic and behavioural responses", (other terms used are a stabler infant, or more behaviourally mature infant.)

Twenty-three studies are reported on the **autonomic** dimension, (of which 9 RCTs), covering heart rate, respiratory rate, oxygenation, apnoea, bradycardia, periodic breathing, temperature, metabolic. With respect to all these it is concluded that SSC provides "a milieu that supports autonomic stability and fosters improvement in basic physiologic functions."

The **motor** dimension refers to muscle tone, posture and body movements. A disorganised neonate has less control, with purposeless extensor movements, most often in response to unexpected stimuli or when sleeping; an organised infant has purposeful, focused and flexor movements. SSC provides containment which induces quiescence and relaxation. Initial reports comparing SSC with incubator babies reported with unusual terms: "outstanding neurobehavioural organisation" (Syfrett et al 1993), and "astonishing maturation, tone, reactivity and spontaneous motor movements" (Colonna et al 1990).

State organisation refers to the ability to appropriately control level of sleep and arousal. SSC results in less deep sleep, much more quiet sleep, and less active sleep. Alert periods, usually scarce and brief in preterms, are longer and more frequent. Crying, shown to be a detrimental state, was "virtually non-existent" or "occurred infrequently".

Research on the **attention/interaction** dimension in infants is scarce, with only descriptive reports. The alertness mentioned above is described first, this was previously almost never seen in premature infants. With SSC however, such alertness occurs more frequently, (even at 30 weeks gestation), but also in a place where parents readily discern it. Included in this topic is also the interaction effects on parents, which have been well researched. Mothers experience less stress, more pleasure and confidence, and a sense of reconciliation, healing and mastery.

Self-regulatory dimension refers to the infants use of "self-consoling behaviours", like sucking and hand to mouth movements. SSC infants are so relaxed and contented such behaviours are hardly necessary. Suckling (breastfeeding) is however one behaviour which SSC dramatically impacts on, with greater maternal desire to breastfeed, greater milk production, and prolonged duration of breastfeeding.

This review concludes: "The spreading acceptance and use of kangaroo care indicate that it is no longer a strategy to consider for tomorrow but one that can be applied today. Some units may sense future shock when urged to implement KC. Future shock, first defined by Alvin Toffler, is the dizzying disorientation brought on by the premature arrival of the future. However, there should be no future shock with KC, ... its acceptance is attributable to the positive outcomes presented here" (Ludington-Hoe and Swinth 1996).

Charpak et al (1996) provide a review from the perspective of the developing world, and also from the perspective of the particular intervention first described by Rey and Martinez (Whitelaw and Sleath 1985). The Kangaroo Mother Intervention (KMI) as defined comprises three components: kangaroo position (=SSC), kangaroo nutrition (= exclusive or near exclusive breastfeeding), and kangaroo discharge (=early discharge regardless of weight, with follow-up). Given Anderson's "exhaustive review" of 1991, this review regards mainly articles published between 1991 and 1995. All the articles in Anderson's review and five new articles identified deal with SSC only, and that in the context of the developed world, all as an adjunct to standard NICU care.

Three articles are identified as applying two of the three KMI components, kangaroo position and kangaroo nutrition. All emanate from the developing world. Sloan et al (1994) and Bergman and Jurisoo (1994) were mentioned briefly in the introduction above, the third is by Colonna et al (1990). Colonna and colleagues described 100 consecutive infants treated in Mozambique. The review criticises the validity of some of the conclusions with respect to reduction in mortality, and the poor weight gain described.

Sloan and colleagues report a RCT from Ecuador, terminated early due to excess severe morbidity in the control group. The review feels little confidence can be placed on the paper's conclusions due to the high attrition rate on followup, and lack of data with regard to compliance to method.

The article by Bergman and Jurisoo (1994) from Zimbabwe is regarded as having a poor design (no concurrent control), but as the historical control included all infants and the method was explicitly described, the conclusions were acceptable. The improved survival supports therefore

kangaroo position and nutrition as an acceptable alternative to technical resources. The review authors suggest that technical resources should still be sought, and that early discharge should be added.

Only one article "evaluated results from applying all components of the KMI", that of Charpak et al (1994), the authors of the review. They compared the intervention practised in one hospital (which lacked resources, serving poor patients) with a control group in a hospital with adequate resources practising standard neonatal care. As originally described by Rey and Martinez, eligibility depended on surviving the stabilisation phase, SSC was started late. The study showed major baseline differences between the groups with regard to socioeconomic circumstances and access to prenatal care. Adjusted relative risk of dying was less for kangaroo infants, but they had poorer growth and higher incidence of developmental delay.

Charpak's review concludes with an appeal for more rigorous research and scientific evaluation of the method, particularly kangaroo discharge and subsequent ambulatory care, longterm sequelae in the infant, and the economic consequences.

A number of articles are categorised as reviews in the MEDLINE, but none lay claim to be systematic or complete (Anderson 1977; Anderson 1989a; Ludington-Hoe et al 1994; Narayanan 1987; Page 1995; Wahlberg 1991; Whitelaw 1990).

There is a Cochrane Collaboration review nearing completion at the moment (Anderson, personal communication, September 1998). The protocol for this review is available on the Cochrane Library site (Whitelaw et al 1998). This review is confined to the North American term "KC" referring to in-hospital skin-to-skin contact. "Volume and duration of lactation" is the first of the listed end-points being examined in this protocol. The background states further that the "full kangaroo care" as introduced in Bogota with early discharge and exclusive breastfeeding, will be reviewed in a separate review.

Current status of Kangaroo-Mother Care

Despite these findings, implementation of KMC has been slow worldwide. At a meeting of KMC workers in Trieste, Italy, October 1996, attended by the author, reasons for this was discussed (Cattaneo et al, 1997). The major factor identified was the lack of scientific randomised controlled trials. A number of other factors were also noted, one of them being the difficulty in interpreting programmes and described practices in various parts of the world. This latter problem is due to lack of agreed definitions. Though this was raised for discussion by the author, available time was used to agree on a single term for "skin-to skin care and breastfeeding", noting that around 30 different terms were is use. Kangaroo-Mother Care (KMC) was agreed to as the standard term. Lack of definitions, parameters and boundaries remain a problem therefore, which has not yet been addressed.

Labbok and Krasovec (1990, see above) described the problem of lack of agreed definitions for breastfeeding. As much as breastfeeding is applied in a variety of ways, even more so is KMC. This was apparent in the multicentre study presented at Trieste (Cattaneo et al 1998). In this study strenuous efforts had been made to provide a standard model of application on five study sites. A variety of factors resulted in a diverse array of differences in the actual techniques and programmes described. In two studies, control groups were denied by the ethics committees, and in one cultural taboos reduced skin to skin contact to almost nothing!

Nevertheless, in certain countries KMC is rapidly gaining acceptance. In a recent survey of the USA (Engler and Ludington-Hoe 1998), 82% of NICU's practised KC (defined as in-hospital skin-to-skin contact) "in some form", though what form was not specified, (52% of all USA NICUs responded). In Germany, skin-to-skin contact is practised in all units, where parents wish it (Sontheimer 1998). SSC is offered on infants of 500 g and 24 weeks upwards, and apart from patients with intercostal drains and narcotic treatment, almost no contraindications are recognised (Sontheimer 1998). The Scandinavian countries likewise have KC as a standard part of normal NICU protocols. Mozambique has officially endorsed KMC as preferred care for prematures (Davanzo 1993), and some other countries in the developing world, e.g. Zimbabwe, have given it formal recognition (Kambarami 1998).

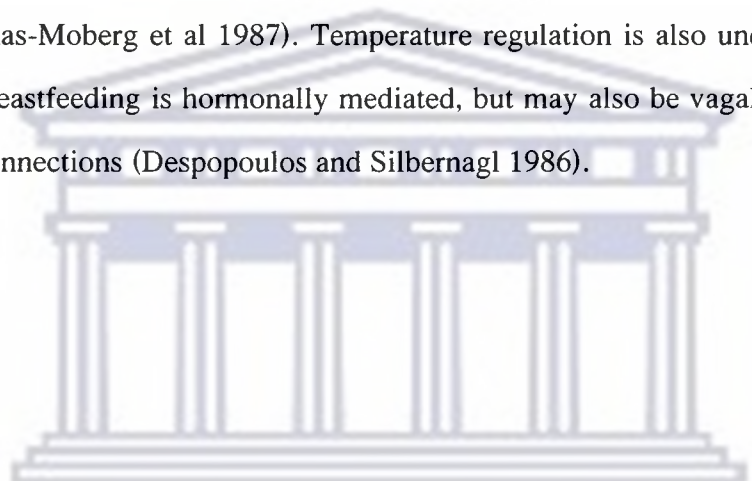
Hypotheses on skin-to-skin contact.

Whereas breastfeeding is well accepted, (though not always well practised), skin-to-skin care is less so. Though much research has in fact been done, it is a relatively new intervention, and has not been disseminated adequately. In the following, current understanding on how and why KMC works will be presented.

Gene Cranston Anderson has researched and written extensively on this, and the following paragraph is condensed from a yet to be published book chapter kindly provided by her. A number of hypotheses and rationales have been proposed, and more than one could be operating, concurrently or sequentially. The "**continuity hypothesis**" refers to the fetus receiving the same stimuli it received in utero, and so is soothed, this promotes mother-infant interaction. "**Crisis and stress theory**" refers to the stressful birth event, then compounded by separation from the mother, with crying leading to problems, SSC prevents or rapidly reduces stress and measurable stress hormones. "**Adaptation hypothesis**" refers to the major physiological adjustments required from uterine to extra-uterine life, stress and crying keep the foramen ovale open, while SSC causes much less crying and regularises respiration, which closes the foramen ovale and leads to better oxygenation which leads to closure of the ductus arteriosus. "**Co-sleeping hypothesis**" refers to the synchronous mother-infant patterns observed, with less deep sleep and less apnoea. "**Preservation of circadian rhythms**" may be related to this. "**Behavioural state**" has been suggested, as SSC causes infants to be calmer and have more quiet sleep, with "**energy conservation**" - which translates to better growth and general well-being. The **improved breastfeeding** and access to **early colostrum** (birth KMC) has been suggested as a rationale for the beneficial effects seen, as has the **avoidance of hypothermia**.

The "**vagal hypothesis**" may underlie most of the above mechanisms. Non-nutritive sucking and skin-to-skin contact are two stimuli able to produce a broad generalised vagal (parasympathetic or cholinergic) effect (Uvnas-Moberg et al 1987). This lowers the deleterious somatostatin in the newborn, and increases levels of all other GIT hormones. This can produce increased weight gain

without addition of calories (Widstrom et al 1988). Early respiratory distress has been successfully treated with SSC and oxygen by mask alone (Argote et al 1991), and the effects observed were similar to those in sheep, where this vagal stimulation was shown to release surfactant in the newborn (Anderson 1975). The energy conservation, regularised heart rates and breathing patterns observed may also be due to vagal regulation (Ludington 1990). Vagal stimulation can also directly counter the adrenergic stimulation in any stressor state (Taylor 1990), and thus avoid the harmful effects of stress hormones. The levels of glucocorticoids measured in incubator newborns approach neurotoxic levels (Modi and Glover 1998), and SSC is able to lower some of those hormones by 74% (Mooncey et al 1997). One of the GIT hormones shown to rise with SSC is cholecystokinin (CCK), which "induces satiety, post-prandial sedation and sleep" (Uvnas-Moberg et al 1987). Temperature regulation is also under vagal control; and the improved breastfeeding is hormonally mediated, but may also be vagally influenced through hypothalamic connections (Despopoulos and Silbernagl 1986).



SECTION TWO SYSTEMATIC REVIEW OF KANGAROO-MOTHER CARE

KMC is a new area of research, and there are at present very few summaries of the findings of the limited research that has been undertaken. KMC at present lacks agreed parameters, definitions and categories for defining the research and interpreting results. This makes it almost impossible for policy makers to interpret vital information required to guide the implementation of a profoundly powerful intervention with its potential to impact infant mortality rates.

BACKGROUND FOR SYSTEMATIC REVIEW OF KANGAROO-MOTHER CARE

Critique of reviews

Three systematic reviews are described in section one. Charpak et al (1996) motivate for the "complete KMI" which includes early discharge. In their review, they note that theirs is the only article in the literature which has all three. In my own view, the early discharge is a practice specific to their particular context, and not one that should be generalised. The initial reason for the early discharge by Rey and Martinez was the high mortality in hospital from cross infections. Early discharge was made possible by the effects of SSC, in providing a milieu that was safe (Ludington-Hoe and Swinth 1996). Charpak et al (1994) report figures showing one third of babies under 2000g died before eligibility (nearly one quarter of control group). The death rate of the KMI babies in the first year was 12%, or 120/1000. These are alarmingly high figures. In contexts where the infant mortality rate is much less, early discharge could quite plausibly increase the death rate, rather than decrease it. Appropriate follow-up for the ambulatory care also requires effort and resources, which can be unattainable in both high density urban areas and sparsely populated rural areas. Doyle (1997) comments on this report, and notes that as recommended by Charpak, "cost of KMC could be prohibitive".

Therefore the view is taken here that KMC as an intervention, consisting of SSC and BF, does not per se include early discharge. It is acknowledged however, in view of the increased daily weight gain, and the increased confidence of mothers, KMC does allow "earlier discharge". Such earlier discharge may have economic benefits to the health service, but then that health service would have to reallocate resources for the "ambulatory follow-up".

Another major criticism of the KMI of Charpak is the rigid adherence to incubators in the immediate post-natal period, and the requirement that the baby must survive the first week to be eligible for SSC. Rey and Martinez originally described SSC applied late, and for babies 1000-1500g claimed improved survival from 27% to 89%. Whitelaw and Sleath (1985) noted that most of the deaths of prematures were in the first week, before they were eligible, and the claimed survival was of a select group of survivors. Most deaths take place in the first two days after birth (Davanzo 1993). Clearly, if an intervention is to have any impact on the real perinatal mortality rate, such an intervention must be aimed at those deaths occurring in the first week, which essentially means from birth. Bergman and Jurisoo (1994) were able to show an improvement in survival applying birth KMC, for the same weight category as above, from 10% to 50%. The total survival of live births in this weight category of late KMC described by Colonna et al (1990) in Mozambique was 37%, a lower survival, despite the availability of incubators and ventilators.

In their review, Charpak et al (1996) argue that health agencies should still "invest in minimal equipment for neonatal care in hospitals". This represents an hospicentric view, out of keeping with the PHC approach. The evidence that Bergman and Jurisoo's article provide is rather that SSC started from birth is at least as good as, if not superior to, the incubator (Davanzo 1993). For the developing world, incubators will remain inappropriate, and in the presence of a potentially superior alternative, health agencies should rather be discouraged from spending money on incubators, and encourage SSC from birth.

From the developed world perspective, a clear trend to starting SSC earlier is apparent. Early articles (e.g. Whitelaw et al 1988) used SSC late in the process and sometimes more for the benefit of the parents than the child! De Leeuw (1991) showed that SSC was safe "even for very

small nonstabilised preterm infants". Ludington-Hoe et al (1993) described complete recovery of 34 to 36 week GA infants with grunting and respiratory distress 17 to 19 minutes post-birth, while receiving only SSC and oxygen by mask. Studying a range of parameters, they conclude "very early kangaroo care, begun in the delivery room, was safe and appeared beneficial" for some infants with distress.

Skin-to-skin contact without breastfeeding.

In North America, the term "kangaroo care" or KC, is generally used for the specific intervention of skin-to-skin contact (SSC). It is generally practised late, and as an adjunct to technologically intensive care. Its beneficial effects appear fairly well established. In research articles, breastfeeding appears however to receive little attention. In most articles it appears that breastmilk or formula is regarded as of almost equal value, and feeding method, whether by bottle cup or breast, likewise.

The advantages of breastmilk over formula and of suckling over sucking, have been presented above. The magnitude of beneficial effects shown is at least in the same order as the effects of SSC, even if the effects are on different parameters. Some of these parameters overlap however. SSC and feeding method both affect oxygen saturation, heart rate and susceptibility to infections, for example. Meier and Brown (1996) noted in their review that "human milk feeding was not standardised", being given in various forms and by various methods, including gavage and bottle. They state "investigators should attempt to standardise this variable in subsequent research". These authors make this statement from the context of what to feed the premature in relation to how to feed the premature, in the absence of SSC. In studying SSC then, the need to "standardise this variable" is just as great.

One of the problems in designing scientifically sound research studies on this subject is that KMC as here defined represents two separate interventions - SSC and BF. It has been noted above that SSC has of itself profound effects on the mothers desire to breastfeed, on the volume of milk produced, and the subsequent duration of lactation.

Neurobehavioural hypothesis.

It may be of value here to recall the anthropological argument. Alberts (1994) describes rats as developing through four habitats (or addresses), the uterus, the mother's body, the huddle of littermates, and the coterie of littermates before leaving the nest. In each habitat, the organism has a niche (or occupation), how it adapts, utilises, responds and copes. At each stage, the organism is seen as being in a stage of completeness, with embodied behaviour and capabilities unique to the niche it has in the appropriate habitat. For example, the human fetus is uniquely and completely organised (or adapted) for life in the uterus: breathing, feeding and excreting through the umbilicus. It then undergoes a transition to another habitat.

I submit here that the habitat for which the human newborn is uniquely organised and adapted is the mother's chest, with skin-to-skin contact. In this habitat, the newborn is able to express the embodied behaviours for which it is completely able and capable. In this habitat the newborn is able to establish bonding and attachment to the mother, and to initiate and sustain breastfeeding. It thus ensures its nutrition, its source of warmth and its protection. There is a logical sequence of events here. Early or immediate contact leads to bonding, which assures its most immediate need following birth, which is warmth. Once warmed, the newborn is able to establish feeding without any help, ensuring its nutrition. Once feeding starts, interactions with the caregiver leads to attachment, which ensures subsequent protection. Thus for these simple and basic needs, the correct habitat is critical.

Developing this theme further, an hypothesis for Kangaroo-Mother Care that encompasses all those reviewed above is possible, the neurobehavioural hypothesis. From the evolutionary perspective, Homo sapiens has already adapted to extreme "immaturity" at birth (McKenna et al 1993). In so doing, following its transition from the uterine habitat to the immediate post-natal habitat, it is more reliant on being in the correct habitat than other mammals. Should it now be born "prematurely" in addition to immaturely, the habitat is even more critical. The neurobehavioural hypothesis proposes that constant maternal-infant skin-to-skin contact is that correct habitat. The mammalian hindbrain enables the premature to behave appropriately in its

habitat. In this habitat, psychophysiological behaviours are able to be expressed, which include inter-actional (bonding and attachment behaviours), endocrine (breastfeeding) and parasympathetic (vagal: all the autonomic functions of thermoregulation, glucoregulation, gastrointestinal, and cardiorespiratory control). This is expressed in other terms by Ludington-Hoe and Swinth (1996), who reviewed SSC research from the perspective of five dimensions of neurobehavioural organisation: autonomic, motor, state, attention/interaction, and selfregulatory, (as originally described by Als, 1986). For each of these dimensions, positive effects of SSC are reported, even though practised late. They state "the potential for KC to make contributions to neurobehavioural development is enhanced if the practice begins early". The neurobehavioural hypothesis proposed here provides an explanation for why this is so, but requires that the "begun early" be from birth without any separation of mother and infant. By this hypothesis, neurobehavioural development is not enhanced by KC, rather, KC is a pre-requisite for optimal neurobehavioural development.

Separation from the mother constitutes a violation of the organism's basic innate agenda. Its programmed response to separation is a survival mechanism, the "protest-despair" response. This response has survival value, but is not conducive to growth and wellbeing. This expresses itself as stress, as described above.

KMC therefore provides two separate, yet critically complementary, interventions. For any human newborn, skin-to-skin contact is the appropriate habitat or address; and breastfeeding is the appropriate niche or occupation. With this perspective, KMC should indeed be regarded as one intervention in its own right. Further KMC should not allow any separation, but by definition should be from birth. Separation from the caregiver is biologically a potentially life-threatening situation (McKenna 1993), and the same psychophysiological responses as are described by Hofer (1994) quickly come into action. The physiological baseline parameters that we have established as normal (?usual) for prematures in the incubator environment are, by the above reasoning, representative of a survival or despair response with physiological slowing "for prolonged passive survival through a combination of conservation of energy and withdrawal from danger" (Hofer 1994). The rise in temperature and heart rate described when SSC (the right habitat) is started, (Ludington and Swinth 1996), is evidence of this.

The human fullterm newborn is, biologically speaking, extremely immature (McKenna 1993). It may be to a higher degree adapted to immaturity than other mammals. Premature birth could therefore be less of a threat to its survival than species with precocial newborns, where their survival depends on their own physical capabilities. The fullterm infant may be better able to cope and adjust to sub-optimal habitats or environments, such as being separated from mother or being put in an incubator. A premature human newborn is however less resilient, and is therefore more dependant on the habitat for which it is "programmed", its mother's chest and breasts. In a highly technical First World environment, the survival of the premature can be assured by mechanical and pharmacological means. In the Third World context, these are lacking, and the stress of being removed from the caregiver is life-threatening in the extreme.

Research implications.

In the research arena the concept of habitat and niches will lead to some complexity. In order for us to understand the effects of the habitat, we need to see the niche as the goal. One could perhaps state it thus: the purpose of SSC is to enable breastfeeding, and breastfeeding is fundamental to the survival and wellbeing of the new organism. Contrast this to the present: in the NICU, breastfeeding is often seen as one of a number of treatment modalities, as important as antibiotics and surfactant, but able to be substituted with a more convenient generic equivalent (=formula).

Research will therefore need to establish the contribution of the habitat and the niche to the subsequent wellbeing of the organism. This will require research with one constant and the other varied. For example, breastfeeding with regard to both what is fed and how it is fed, must be constant in order to interpret the impact of alternative habitats, in this instance say the incubator versus the mother. And, SSC should be a constant in studying the effects of breast milk versus formula, should it be possible with regard to the newborns capability to choose what is best for it. In terms of implementing an intervention, by the evidence and the neurobehavioural hypothesis presented above, the focus of the intervention should not be the niche or occupation (the

breastfeeding), as at present (e.g. the BFHI). **The focus of the intervention should rather be to provide the correct habitat** or address. Once that is accomplished, the newborn will see to the rest. From this hypothesis would follow: enormous effort is required to ensure breastfeeding of a premature in the absence of SSC, very little will be required when it is fully provided.

Sinclair (1992) discusses assessing evidence concerning treatment of diseases of the newborn. After regarding effect, bias and precision of a trial, generalisability should be considered. Here he provides a helpful distinction between explanatory trials versus management trials. Explanatory trials ask how effects are produced, and require tight control under ideal or restricted circumstances. The real world is seldom able to be controlled like that. Management trials are more directly applicable to clinical practice. Assessing management trials also requires considerations as to effect, bias and precision, but in addition interpretation requires very careful assessment of the context and the specific group studied. Extension of conclusions from one context or from one group to another should not be done without another RCT. Care should be taken to consider patient centred outcomes like death or major morbidity, rather than risk factors or surrogate end points. Late outcomes and mortality and morbidity from other causes should also be considered.

An example of the latter could be the comparison of growth rate between breastfed and bottle fed infants. It has been well established that bottle fed infants grow faster. Faster growth is a surrogate end point, which could be assumed would translate to better wellbeing with less morbidity and mortality. The opposite is in fact the case.

With regard to what is presently known about KMC, there is in fact an urgent need for both explanatory and management RCTs. Enough is however known from explanatory RCTs, for management randomised controlled trials to be conducted, though much detail in terms of the explanatory is also required.

Rationale for this review

In conclusion: worldwide, 96% of the worlds premature babies do not, and will not, have access to incubators. They do however have access to something possibly superior - which our culture and our ignorance presently denies them - skin-to-skin contact with their mothers. Given that prematurity is the single most common cause and contributory factor to neonatal mortality worldwide, and given the potential benefit of an intervention which requires no significant financial resources, the investigation and implementation of KMC is a public health imperative.

OBJECTIVE

The objective of this systematic review is to review the skin-to-skin contact component (kangaroo position) of Kangaroo-Mother Care specifically, and to examine breastfeeding (kangaroo nutrition) in this context. This review, in the biological parlance of neurobehaviour, examines research articles in which the habitat (SSC) is correct, and examines the niche (breastfeeding) within that habitat.

The purpose for this is to critically examine the claims and merits of KMC and SSC particularly, so as to make recommendations for practice and for further research.

METHODS

A systematic review can be done in a number of ways, and is basically defined as a planned review of any subject, where the reviewing method is described beforehand and systematically followed. A Cochrane Review is a systematic review confining itself primarily to randomised controlled trials (RCTs) or clinical controlled trials (CCTs). Their view is that only these kinds of trials can provide results which avoid bias or chance, and that by reviewing them systematically and together, a reader can "find the results of research quickly and assess the validity, applicability and implications of those results" (Mulrow and Oxman 1996).

A visit was made to the Cochrane Centre at the Medical Research Council, Parow, on the 25th August 1998. Dr J Volmink very graciously explained the function of his centre, of the Cochrane Collaboration, and of systematic reviews in general. He also provided literature and a handbook. The handbook describes in detail the process of the systematic review as done by the Cochrane Collaboration. A "visit" was also made to the Cochrane Collaboration's internet site. This systematic review cannot be as rigorous as a Cochrane review, but as far as practical, the principles of such a review have been followed.

Selection criteria.

Studies. For systematic review, only articles which contain a control group were included. This included case control studies and historical controls, but excluded descriptive studies and case reports.

Participants Participants were all subjects on which the intervention was applied. These were studied in two subgroups, the one comprising studies on premature infants, and the other on fullterm infants (at lower risk).

Intervention. The intervention being reviewed as a starting point was SSC. This is seldom referred to as such, the word "kangaroo" is most commonly used.

Outcome measures All outcome measures reported were considered. These were grouped according to patient centred outcomes and surrogate endpoints. The former included reported mortality and morbidity rates, the latter included properly described and defined physiological, psychological and behavioural outcomes, chief of which was breastfeeding.

Search strategy.

The search strategy was focussed on articles that have been published in the literature. Though this may be incomplete, it has the advantage of being rapidly reproducible to clinicians encountering requests to implement KMC, and for policy makers seeking to implement KMC as part of public health policy. It is acknowledged that there may be a certain bias in selection, in that results of studies that may not have been favourable have not been published. To a minor extent, the search strategy was complemented with information received from personal contacts with researchers.

Collection methods

The initial search was on MEDLINE, which is accessible free on the Internet. This was from 1985 onwards, when KMC was first reported (Whitelaw and Sleath 1985). Search terms included "kangaroo" and "skin-to-skin".

It is recognised that MEDLINE only includes one third of all journals in which trials could be published, and that some research could have been published in journals not included in the medical databases. Again this might result in a bias to a more favourable outcome.

A "second pass" was made by scrutinising the reference lists of the articles located as described above, additional articles were found this way.

Most of the journals with these topics were found at the University of Stellenbosch Medical School Library. Access to these is gratefully acknowledged.

Critical appraisal

All articles collected were assessed, those identified as meeting the inclusion criteria are marked ** in the References, see also Appendix 2. Those that meet the criteria for inclusion were grouped in three categories according to study type: RCTs, interrupted time series, and historical controls. These were tabulated, and the main findings extracted. Methodological flaws and other problems were identified in a critical appraisal as per Cochrane guidelines.

Four areas of potential bias were explicitly assessed: selection bias, performance bias, attrition bias, and detection bias. **Selection bias** is avoided by ensuring allocation concealment, whereby no foreknowledge of assignment is possible, and where once eligibility is fixed allocation is likewise fixed. This bias receives the most attention by Cochrane reviewers. **Performance bias** refers to ensuring that care to the groups being compared is identical in every way except the intervention being studied. **Attrition bias** refers to losses of subjects from either group that would make the result questionable. **Detection bias** refers to methods in assessing outcome of the two groups being different, and also to selective reporting of results for any outcome preferred by the reporter of the trial. Each article was examined explicitly for any possible bias on any of these four areas. Each of the four biases were scored as to adequate (A), unclear (B), inadequate (C), or

not used (D). If all criteria were met adequately, the trial in total was regarded as having a low risk of bias (A). If even one or two criteria are only partly met, and there could be any plausible bias, the trial was ranked as having moderate risk (B). If one or more criteria are not met, and confidence in the results reported were seriously weakened, the trial was ranked as having a high risk of bias (C).

RESULTS

The MEDLINE search yielded several unwieldy lists in which articles often appeared several times.

107 articles concerning SSC in some were considered in this review. (See reference list for details).

There were 14 articles on trials in which randomisation occurred, though a variety of variables were examined in a variety of contexts. There were 12 studies using interrupted time series, and 3 using historical controls or retrospective analysis. In all 29 articles are included in this analysis.

See Appendix 2 for details.

The studies are identified by the "author date" code, full details are in the references.

The main data extracted from the articles are tabulated by participants, description of the intervention and control group, fixed variables, outcome measures, comments and flaws, and notes. The critical appraisal is shown in the column "comments and flaws".

Randomised Controlled Trials

Using the guidelines with regard to different kinds of bias proposed by the Cochrane Collaboration, only three RCTs appeared likely to have no significant bias (Christensson et al 1992, Christensson et al 1995, Whitelaw et al 1988), and three showed very slight possibility of bias, all on basis of performance bias (Anderson et al 1998, Johansson et al 1992, Swinth and Ludington-Hoe 1998).

Table 3 Randomised Controlled Trials

Author date	A	B	C	prem	term	bssc	vssc	essc	issc	lssc	Hrs
Christensson 1992	x				x	X					24
Christensson 1995	x				x	x					24
Johannson 1992	x			x	x	x					24
Michelsson 1996		x			x	x					1.5
Syfrett1993			x	x		x					24
Anderson 1998	x				x		x				6
Durand 1997			x		x		x				24
Kambarami 1998			x	x					x		24
Whitelaw 1988	x			x						x	0.6
Swinth 1998	x			x						x	1
Blaymore 1996		x		x						x	0.2
Kronson 1996		x		x						x	1.9
Sloan 1994		x		x						x	24
Charpak 1997			x	x						x	24

A = little likelihood of bias, B = some bias possible, C = bias significant prem = premature, term = fullterm infants, bssc = birth SSC, vssc = very early SCC, essc = early SSC, issc = intermetidate SSC, lssc = late SCC, Hrs = duration of SSC in hrs per day.

Regarding the initiation of SSC, it is noteworthy that all of RCTs on birth or very early SSC were done on term infants, with one exception. Syfrett and Anderson (1993) is a conference report on a pilot study involving 4 infants in each group, randomised and comparable. The four SSC infants appeared to fare much better than the controls with regard to breastfeeding, length of stay, and complications, with none being admitted to the NICU compared to three of the controls. A full trial is still being conducted, data not yet published.

Non-randomised trials

Table 4 Non-Randomised Trials

Author date	A	B	C	prem	term	bssc	vssc	essc	issc	lssc	Hrs
deLeeuw 1991	x			x					x	x	1
Bosque 1995	x			x						x	4
Fisher 1998	x			x						x	2
Ludington-Hoe 1990	x			x						x	2
Acolet 1989		x		x						x	0.2
Legault 1995		x		x						x	1
Ludington-Hoe 1991		x		x						x	2
Ludington-Hoe 1994			x	x						x	3
Messmer 1997			x	x						x	1
Mooncey 1997			x	x						x	0.4
Bergman 1994		x		x		x	x			x	24
Affonso 1989			x	x					x	x	3
Charpak 1994			x	x						x	24

A - little likelihood of bias, B some bias possible, C significant bias likely

bssc birth SSC, vssc very early SCC, essc early SSC, issc intermetidate SSC, lssc late SCC, Hrs = duration of SSC in hrs per day. The historical controls are included here, but cannot be accorded "A bias status".

By the very visible nature of the intervention, and the heterogenous application of it, unbiased RCTs appear difficult to conduct. In this regard, the interrupted time series trials may have to be accorded more importance than in other contexts. Note here also that all the latter group of trials are on premature infants, and apart from the study by Bergman and Jurisoo (1994), all are late SSC.

General outcomes.

Pooling the conclusions of all the above trials in which the likelihood of bias is low, certain conclusions appear safe to make. Firstly for term infants, SSC is safe with regard to thermal control, glucoregulation and cardiorespiratory function (Anderson et al 1998, Christensson et al 1992, Christensson et al 1995, Johansson et al 1992).

Table 5 Summary of effects found in all trials with unlikely bias.

Author date	term	prem	T	Resp	Card	Beh	Mat	BFR	BFD	Other
Anderson 1998	x									Cortisol lower (+)
Christensson 92	x		+	+	0	+				Base excess diff (+)
Christensson 95	x		+			+				
Johansson 1992	x		0							
Swinth 1998		x								Phototherapy ISQ (x)
Bosque 1995		x	0	0	0	+				
DeLeeuw 1991		x	0	0	0	0				Safe in very small
Ludington 1990		x			0	+				
Ludington 1994		x	+		+	+				
Whitelaw		x	0			+	0	+	+	

T = temperature, Resp = composite of respiratory effects, Card - composite of cardiac effects, Beh - behaviour and sate of infant, Mat - composite of effects on mother, BFR breastfeeding rate, BFD breastfeeding duration,
+ = better or improved, 0 = no change, - = worsened

The outcomes measured in all of the above trials were either in favour of SSC or showed no difference to controls. Significant outcome measures which have not been included in the above trials include the daily rate of growth, neonatal and infant mortality, neonatal and infant morbidity, duration of hospitalisation.

The possibility of reporting bias would have to be considered in this regard. However, the results are consistent within the trials. Many of the findings show statistical significance, but may not necessarily have clinical relevance, for example the changes noted in temperature and heart rates.

With regard to duration of SSC, none of the "unbiased" trials include SSC beyond four hours per day. Regarding all the trials considered, duration of SSC varies from 10 minutes per day through to 24 hours per day - representing a very varied or heterogenous application of the intervention.

Patient centred outcomes.

From this review, there is no trial providing firm evidence with regard to mortality and morbidity, all the trials report surrogate end points.

Only two trials report significant improvements in mortality rates, both from Zimbabwe: one from a tertiary centre (Kambarami et al 1998), and one from primary level care (Bergman and Jurisoo 1994).

A number of articles report on morbidity, generally suggesting KMC to be safe, with no more infection than by CMC. Better designed trials excluding bias are needed to confirm these reports.

Breastfeeding.

Breastfeeding, the intended niche of the organism in the habitat, is the second major focus of this review. Of the "unbiased" trials, only the article by Whitelaw et al (1988) reported findings on breastfeeding, which were that duration of breastfeeding was significantly longer and a greater proportion of mothers were breastfeeding. Significantly, this was on very small premature infants with an average of 36 minutes SSC per day. Analysis of milk given, method used, and breastfeeding outcomes follow.

Table 6a Analysis of information regarding effects of SSC on breastfeeding.

Author date	A	B	C	prem	term	Hrs SSC	No info	BM	Form	Breast	Bottle	BM vol	BFR	BFD
Acolet 1989		x		x		0.2	x							
Affonso 1989			x	x		3	x							
Bergman 1994		x		x		24		x		x				
Blaymore 1996		x		x		0.2		x		x		+	+	+
Bosque 1995	x			x		4		x	x	x	x			
Anderson 1998	x				x	6	x							
Charpak 1994			x	x		24		x	x	x	x		+	
Charpak 1997			x	x		24		x	x	x	x		+	
Christensson 92	x				x	24	x							
Christensson 95	x				x	24	x							
deLeeuw 1991	x			x		1	x							
Durand 1997			x		x	24		x		x				
Fisher 1998	x			x		2	x							
Johannson 1992	x				x	24	x							
Kambarami 1998			x	x		24		x	x	x	x			
Kronson 1996		x		x		1.9		x		x			+	
Legault 1995		x		x		1	x							
Ludington 1990	x			x		2	x							
Ludington 1991		x		x		2	x							
Ludington 1994			x	x		3	x							
Messmer 1997			x	x		1	x							
Michelsson 1996		x			x	1.5	x							
Mooncey 1997			x	x		0.4	x							
Sloan 1994		x		x		24		x		x			0	
Swinth 1998	x			x		1	x							
Syfrett1993			x	x		24		x		x			+	
Whitelaw 1988	x			x		0.6		x		x			+	+

A = little likelihood of bias, B = some bias possible, C = significant bias likely
Hrs SSC = hours per day on SSC, No info = breastfeeding as variable/outcome not considered/reported, BM = humna breast milk, Form = formula feeding, BM vol = breast milk volume, BFR = breastfeeding rate, BFD = breastfeeding duration,
+ = better or improved, 0 = no change, - = worsened

Only 11 of the above 27 trials provide information on breastfeeding or other feeding methods. For some of the articles, the purpose, context and the timing of the trial make such information unnecessary or irrelevant, but for some the feeding method and feeding content could affect the very variables being considered. In the following table, results of these 11 trials are presented.

Table 6b Analysis of information regarding effects of SSC on breastfeeding.

Author date	A	B	C	Hrs SSC	Outcome or comment	KMC	CMC
Bergman 1994		x		24	Essentially all breastfed on discharge		
Blaymore 1996		x		0.2	Breast milk volume change from baseline	+10%	-15%
					Breastfeeding rate at discharge	90%	61%
					Breastfeeding rate at one month	50%	11%
Bosque 1995	x			4	Repeated measures design, all breastfed		
Charpak 1994			x	24	Breastfeeding rate 40 weeks PCA	93%	78%
					Breastfeeding rate at 6 months	70%	37%
Charpak 1997			x	24	Very high breastfeeding rates both groups		
Durand 1997			x	24	Study compared breastmilk and formula		
Kambarami 1998			x	24	Not considered or studied		
Kronson 1996		x		1.9	Breastfeeding rate at discharge	100%	71%
					Breastfeeding rate at two months	93%	57%
Sloan 1994		x		24	Very high breastfeeding rates both groups		
Syfrett1993			x	24	Number of breastfeeding per day given	12	2
					Breastfeeding rate at discharge	4/4	1/4
Whitelaw 1988	x			0.6	Mean duration of breastfeeding in weeks	9.2	5.1

Only 7 of the trials report breastfeeding volumes or rates or durations. All but one report positive effects, the one not doing so was in a context where breastfeeding was already very high. Kronson's (1996) study is flawed in this particular respect in that mothers self-selected the SSC option, it is possible that mothers who did so would also be more likely to breastfeed also. In Blaymore's (1989) study, allocation of subjects was done where eligibility included intention to breastfeed, and where mothers were expressing milk, which was the same for both groups. Care was also taken to give the same breastfeeding support to both groups. The improved breastfeeding outcome can therefore probably be attributed directly to the SSC provided, which was only 10 minutes per day for ten days (the least "dose" of SSC in studies assessed). In the review by Anderson (1991) results of a trial by Schmidt and Wittreich (1986, unpublished paper, not obtained) are reported: SSC mothers expressed 640ml per day compared to 400ml per day for controls.

ANALYSIS

For term infants, SSC from birth provides good thermoregulation, the strength of this evidence is good. There is also adequate evidence that SSC babies cry far less than babies separated from their mothers. The interpretation that this cry is a "separation distress call" is appealing and convincing, but lacks proof at this stage.

For premature infants, there is no published randomised controlled trial of sufficient rigor on SSC from birth to draw any conclusions. A single report using a historical control, (Bergman & Jurisoo 1994) of acceptable design (Charpak 1996), suggests positive effects on mortality; however such studies do not by the criteria applied warrant "A rating" in terms of possibility of no bias.

For premature infants, SSC practised subsequent to birth, whether in unstable or stable infants, has been adequately researched, and can be regarded as safe, and in certain circumstances, beneficial.

No harmful effects of SSC have been reported.

There is a paucity of research conducted in disadvantaged communities.

CONCLUSIONS

The general conclusion of the above systematic review is that there is good evidence that SSC has positive effects, and that it has a close relationship to breastfeeding. There are however significant gaps in our knowledge and understanding of the background and mechanisms involved. The rate of progress in terms of implementation appears slow, except in the USA, where one third of NICUs currently practice KC (Gale and Vanden Berg 1998), and possibly more (Engler and Ludington-Hoe 1998).

Implications for practice

Though SSC may on the surface appear a standard term, it is clear from the above analyses that it represents a very heterogeneous intervention with respect to a number of variables. In order to properly understand the interventions from both a clinical point of view and from a public health policy point of view, it is vital that all these variables are clearly expressed and explained.

With respect to the SSC itself, the time of initiation is the first important variable, and a subsequent variable is the duration, or continuum of SSC provided. From the neurobehavioural hypothesis presented above, SSC should ideally be practised from birth and be continuous. Research has been thus far aimed mainly at SSC practised late and for short periods, and findings analysed above do show positive effects.

Other variables that appear in the studies are the weight of the infant, some of which are reported as birthweights and some as the weight when late SSC is started. The gestational age is generally regarded as a more important indicator of prognosis or outcome, but is less often reported. The stabilisation and general health of the infant are also variables to be considered, noting reports of using SSC to treat infants with respiratory distress successfully (Argote et al 1991).

The relationship of SSC to breastfeeding is more complex, in that the feeding method and the feeding matter can both affect the wellbeing of the infant, in the same way that SSC per se can do, whilst SSC per se is able to affect the ability to breastfeed, and the subsequent metabolic utilisation of the ingested milk. Again, the neurobehavioural hypothesis provides a logical explanation for this relationship, in that the SSC provides the environment in which the behaviour of breastfeeding is intended.

Framework

A descriptive framework is therefore proposed here. The intention is that whether for research from an explanatory perspective or from a management perspective, a full set of variables need always to be included. For explanatory RCT's, the variables need not only be mentioned, they should also be accounted for, or standardised. The framework can be applied to a single infant to accurately define the KMC provided, it can also be used to define specific categories within care or research protocols. (See Table 7 below). The full motivation for the categories suggested is beyond the scope of this paper. They are primarily based on physiological and prognostic cut off levels, and many are already used by researchers. It is important to note that all the context parameters and all the care parameters are independent of each other. There are a number of variables which have not been included in the above. The above should really be seen as a minimum data set, and additional data should be added as indicated.

Policy makers will require more than the clinical perspectives of such researchers. For them, the context of any research finding is critical. It is therefore vital to clearly define the context in which any explanatory or management RCT is conducted, and to provide such information as to enable policy makers to interpret the generalisability of the research conclusions. This context is in many respects the first information set needed, and is therefore presented first.

The **key context variables** suggested are "world" (referring to developing/Third/South, or developed/First/North), resources and patient pressure. Under context variables, the level of care (primary, secondary and tertiary) could be included. This can be misleading however, as certain assumptions could be made about tertiary level of care which are erroneous. For example, in Addis Ababa the tertiary level hospital for the country does not have ventilators for newborn infants (Cattaneo, Trieste, personal communication). Thus it is more relevant to define the equipment available. Respiratory distress is the commonest cause of death for premature infants (Anderson 1975), and the equipment for the management of this should be listed. The categories for patient pressure are quite subjective, but represent a composite of a variety of data which is difficult to standardise. Additional information could/should be given to support the chosen

designation. Particularly important is the PNMR and the IMR in the town or district or country concerned. This is often not known, but the "hospital PNMR" should then be given. Bed occupancy rates, length of stay and patient/staff ratios would also support chosen levels. The need for early discharge as defining for KMI (Charpak 1996) is related to this item.

Breastfeeding rates may have relevance, as may aspects of local culture relating to breastfeeding behaviour. Management deals with inputs and processes as well as outputs and outcomes. Staff and resource shortcomings may be the cause for high mortality rates; adequate resources is however no guarantee of low mortality rates. The kind of care given is often determined by the birth weight and the gestational age of the newborn, and as these are "given" they are included under the general heading of context variables.

There are a large number of context variables that are generally reported and not included here (e.g. mothers age, race, socio-economic status, educational status), where these have relevance they should of course be included. One factor which is not included in the framework is the classification of SGA, AGA and LGA (small, appropriate and large for gestational age). These categories are derived from the GA and the birthweight (Ballard et al 1991; Lubchenco et al 1966), which are included in the framework, but it is accepted that in many circumstances it will be necessary to analyse results with respect to these. The respiratory support appears as both a context and a variable: in resource poor contexts there are often protocols which determine the use of equipment, the availability of it does not necessarily mean any individual patient or group of patients benefits from it.

The **key care variables** suggested are the timing of initiation of SSC, and its continuum, that is the amount of time per day it is provided. This summarises the "habitat", the "niche" requires information of the nutrition provided and the method of delivery. The care able to be provided depends primarily on the context, however, as a single sensitive indicator with major prognostic import, "respiratory support" is suggested as the key variable.

This framework could be used to describe the particular configuration of KMC an individual infant is given in a point in time, or it can be used to define the categories under which larger

groups of infants are analysed and described. For a policy maker to make comparisons between trials addressing the same parameters, conclusions can not be drawn if one reports a group between 1000-1500g and another reports 1200 to 1700g. The categories suggested for weight and gestational age were discussed and agreed at the first International Workshop on KMC at Trieste, Italy, in November 1996. The categories for timing and continuum are proposed by this author, and are based on the neurobehavioural hypothesis and physiological observations.

Table 7 Descriptive Framework for Kangaroo Mother Care

CONTEXT					
World	South/Third				North/First
Resources	None/Poor (no incubator)		Some (incubator)		Adequate (ventilator)
Patient pressure	High		Moderate		Low
Mass of baby	ANY	>1.8kg	1.5-1.8	1.2-1.5kg	<1.2kg
Gestation	ANY	>34w	32-34w	28-31 w	<28 w
CARE					
Timing of SSC start	Birth no separation	Very early < 90 min	Early >1.5 -<7 hrs	Intermediate >7h - <7d	Late >7 days
Continuum of SSC	Continuous 20- 24 hrs	Intermittent 12 -20 hrs	4 -12 hrs	1-4 h	<1h
Food	Breast only	Expressed BM	Drip, IV	Formula+ Breast	Formula
Method	Breast	Cup, spoon	Catheter	NGT	Bottle
Respiratory support	None	O2 by mask	O2 controlled	CPAP	Ventilator

BM = breast milk, w = weeks, IV = intravenous, NGT = nasogastric tube, O2 = oxygen, CPAP = continuous positive airways pressure.

Implications for research

The above framework can be made into a matrix to direct research needs. Clearly the findings of any RCT need also to be verified for different contexts. For example, the early discharge defined as part of the KMI in Bogota has above been attributed to high patient pressure, research should establish whether early discharge is appropriate in contexts of moderate or low patient pressure. Ethics committees may however be unwilling even to agree to such trials.

With regard to the variables, the safety and efficacy of KMC should be tested in each weight group and each gestational age group. As can be seen from the Table (Randomised Controlled Trials), all the "unbiased" trials have been performed on term infants, the same trials should then be conducted on the next group with lower gestational ages and birthweights, until it is established to what minimum level the intervention can be applied.

However, there are two specific areas in which research should be prioritised, that of birth SSC, and that of breastfeeding in this context. As was presented in the introduction of this section, the investigation of an intervention that can significantly impact on infant mortality rates is a public health imperative.

In the following section, a proposal for a RCT addressing this need will be presented. The layout of this follows that described by Katzenellenbogen et al (1997), with certain modifications influenced primarily by material supplied by Gene Cranston Anderson, and by Adriano Cattaneo from the multi-centre study conducted from Trieste.

SECTION THREE RESEARCH PROTOCOL

STATEMENT OF PROBLEM/AIM

The incubator predates the randomised controlled trial by some 60 or 70 years. Whereas newer technologies have been subjected to RCTs since the 1960s, the use of the incubator, and the "necessity" for separating the newborn (premature or not) from its mother, was always taken for granted. The incubator as an intervention has never been subjected to a RCT. Part of the reason for this is the lack of any known and feasible alternative. Kangaroo Mother Care does provide such an alternative, and the anthropological and physiological research results described above bear powerful testimony to this.

Though much basic research suggests that (birth) KMC is at least as safe, if not better, than CMC, there is at present no randomised controlled trial(s) of sufficient rigor on SSC started from birth on low birth weight infants, on which governments can base their policies and clinicians can change their practice.

OBJECTIVES

Skin-to-skin care has been shown to minimise newborn crying, improve the neurobehavioural state, ensure thermoregulation, and optimise cardiorespiratory functions through a broad parasympathetically governed (vagal) response. The purpose of this research is therefore to compare the use of incubators and mother's skin-to-skin contact, with a view to establishing the safety and efficacy of the latter, or otherwise.

The research will seek to prove the overall premise that these infants, though vulnerable, have the potential to stabilise physiologically and avoid admission to the neonatal intensive care unit, provided they receive skin-to-skin contact with their mothers from birth. It will seek to establish the safety of KMC as an alternative to CMC.

The broad long term objective is to develop an effective acceptable and easy to implement model of mother-infant care, for world wide use.

Hypotheses

Primary hypothesis (=H, NH= null hypothesis)

H SSC from birth is superior to incubator care (CMC)

NH There is no difference between SSC from birth and incubator care.

H1 At six hours, SSC will have fewer NICU admissions than CMC

NH1 At six hours, SSC will not result in fewer admissions to NICU compared with CMC

Measures of adaptation:

H2a SpO2 (oxygen saturation, adjusted for inspired O2,) will be better for SSC

H2b During the six hours, there will be fewer episodes of apnoea in KMC

H3 At six hours, pulse rate will be lower in KMC group

H4a During the six hours, there will be fewer episodes of hypothermia in KMC

H4b During the six hours, there will be fewer episodes of hyperthermia in KMC

H5 During the 6 hours there will be less hypoglycaemia in the KMC group.

H6 Composite stabilisation score 5 – 6 hours better with KMC

H7 KMC group will have fewer complications up to discharge.

STUDY DESIGN

This will be a **management RCT**, in that it will compare a total method of care with more than one component, against the conventional method of care. It will do so in a total service setting, including primary levels of care referring to secondary hospitals and an academic tertiary hospital with neonatal intensive care units with high standards of care, though functioning under resource constraints. Present policy restricts ventilation to babies above 1000g.

Mothers with preterm labour will be identified before delivery, to ensure the presence of a trained nurse researcher at the birth. This will require the cooperation of the obstetricians and the midwives in labour ward, to identify all potential candidates in good time, and to allow time for informed consent to participate in the trial to take place. The randomisation preparation will be started on the mother's information, with informed consent being obtained before delivery. The immediate care of the newborn will be the same for the first five minutes, during which final eligibility of the infant will be established. The management for these first five minutes will be made on the basis of avoiding any separation between mother and child, and will involve a minor modification to the current CMC. The minimisation method will be used to randomise, see below.

Basic data on excluded and refusing mother-infant dyads will be collected. Complete records/information from the whole PMNS information system will be requested during the trial.

The intervention will consist primarily of SSC versus incubator, and the SSC group will also be provided with opportunity, encouragement and help for breastfeeding.

Setting

The PMNS (Peninsula Maternity and Neonatal Service) has two maternity hospitals and five midwife obstetric units, with some 21500 deliveries per year. The system is able to pick up the majority of low birthweight babies antenatally/intrapartum, so that the majority actually deliver in secondary or tertiary hospitals, where optimal neonatal care is available. The PMNS is based on Midwife Obstetric Units (MOUs), run by professional nurses, with all management of cases driven by care protocols. The "premature labour" pickup rate of the midwives is good (above 70% for all LBW, higher for smaller babies). Within the referral units, to which all high risk

deliveries are referred, management protocols are also in place, for "premature labour", which are able to identify potential low birthweight babies. This setting will enable time for the above randomisation to take place. For the duration of the trial, providing additional information required for the randomisation will be added to the care protocol. Mowbray Maternity Hospital and Somerset Hospital are the secondary units for deliveries, Groote Schuur Hospital is the tertiary unit, however both secondary units have tertiary level NICU's for newborn care.

The LBW rate in the Western Cape is high, perhaps related to a very high prevalence of smoking among young women.

The trial will be initiated in Mowbray Maternity Hospital. Mothers delivering here have no anticipated medical problems, and the exclusion rate of eligible mothers is likely to be less. Once recruitment procedures and observations are going smoothly, recruitment of subjects will begin at Groote Schuur Hospital. Only if recruitment is very slow will it be necessary to use New Somerset Hospital, which is geographically isolated.

The hospitals are functioning under extreme pressure of work, with staff cuts driven by major budgetary cuts. In this context, it will be necessary to ensure funding for the entire study period, and all the resources required.

Four registered professional nurses with neonatal care experience will be recruited, and will undergo training and preparation for the study during a two week period, organised fulltime by the principal investigator. Before the start of the trial they would all be trained in the care of the mother-infant dyads according to the intervention method, and some standardisation of the conventional method of care done. They would also provide information to the MOU's to facilitate consent and minimisation. For one week, they would all work some normal and some after hours in the hospitals, to familiarise themselves with routines and to establish good working relationships with the ward nurses, both in labour ward and the neonatal units. For the first two months, one of the nurses at a time will be constantly present in the unit (and perhaps the MOUs) to ensure optimal recruitment of subjects, and streamline procedures.

Should it be used, these nurses would be responsible for operating the minimisation software, which would be prepared for them. They should ensure coordination and cover for the study period, and would cover for each other (24 hours a day and weekends), to ensure coordination and continuity, completeness of records, and quality of data. Having the same four nurses would

ensure control of method for both groups, and ensure no contamination between groups, and pick up any violations of protocol in either arm.

Approval for these nurses to conduct their work for the study in the hospitals will be obtained from hospital authorities and the ethics committee. They will require full registration with the Nursing Council, and own indemnity insurance.

Table 8 Statistics from the setting (PMNS 1997 data)

Sites	GSH	MMH	NSH	Subtotal	MOU	ALL
Number between 500 -999g	95	34	49	178	81	259
Number between 1000 -1499g	201	114	105	420	85	505
Number between 1500 -1999g	**273**	**205**	**249**	**727**	**175**	**902**
Number between 2000 - 2499g	689	224	410	1323	777	2100
Total low birthweight	1258	577	813	2648	1118	3766
Total live births	3980	5381	4796	14157	11221	25378
Total stillbirths	237	148	127	512	144	656
Caesarean section births	1670	1866	1435	5178	0	5178
Number BBA at units	167	528	126	821	761	1582
Perinatal mortality rate per 1000	82	38	36	52	15	36
Early neonatal mortality rate	19	11	10	12	3	8

Proportion born at MOUs, 44%
Proportion referred by MOU for care 3.5%

Breastfeeding rates for fullterm and for premature infants are not precisely known, but are generally poor, exclusive BF after the first month is rare, and even partial breastfeeding beyond 5 months is rare.

For a control group in a small KMC intervention study (Kronson 1996), breastfeeding rate on discharge (BFRD) was 71%, and at two month follow-up (BFR2) was 57%. (For KMC group these figures were 100% and 92%).

Study population (sample characteristics)

The study population will consist of mothers who qualify, and subsequently their newborn who qualify.

Antenatal clinics will inform all mothers of the trial at their first attendance (booking visit), and the possibility of being included in it. MOU's referring mothers in preterm labour will give "precounselling" as to the trial, with the help of written material translated into all three languages, and help with consent to enter trial. (See Appendix 3 for sample consent form) Preparations for randomisation must essentially be completed prior to delivery.

Mothers must be identified as likely to deliver a low birthweight infant before the actual birth, with enough time to ensure informed consent to the trial, and gather basic maternal data. Exclusions will be mothers delivering outside the unit (e.g. transfers, born before arrival); and mothers having C/S or being too severely ill to be able to look after themselves or their infants. Mothers who are known to have positive HIV status will be excluded, even if they have indicated their intention to breast-feed. PIH (a common association with LBW), need not per se be an exclusion, only if so severe as to effect the mother badly. Multiple births will not necessarily be excluded, unless practical complications arise; SSC is quite practical with twins, a bit more problematic with triplets.

Newborns between 1500 and 1999g, born of eligible mothers, with Apgars above 6 at 1 minute, with no major congenital malformations will be eligible for randomisation.

(See Appendix 4, page 1)

Randomisation (allocation) and sample size

Randomisation of 100 mother-infant dyads will take place at 5 minutes of age, after basic assessment and weighing. This sample size is expected to be adequate for the expected outcomes, see more below.

Once any newborn is eligible, the computerised minimisation method will determine allocation to standard or conventional method of care, CMC (control group), or to skin-to-skin contact, KMC (intervention group).

Once allocated, dyad remains in group. If incubator clinically or otherwise indicated for infant allocated to KMC, dyad can return to SSC later. To avoid contamination, dyads will be cared for in separate wards as far as hospital facilities and infrastructure allows.

The ***minimisation method*** is a computer technique, whereby potential confounders identifiable in advance of randomisation of the subject entering the trial are fed into the computer, which does the assignment, and ensures the two groups of subjects are evenly matched for those confounders. This software has been provided by Gene Cranston Anderson, (Zeller et al 1997). Likely minimisation factors for the mother could include race, smoking, alcohol, opiates or sedatives, gestational age by LMP, oxytocin in labour, epidural, anticipated delivery method, parity, age, PIH. Factors for the infant could include sex, actual birth weight, and Apgar score. (Gestational age would be accurately confirmed later, would not be an independent variable, with respect to gestation by last menstrual period.) The minimisation would be done on a portable laptop computer.

Protocol for both groups

For SSC babies the nurse researchers will provide the care, as well as perform the standard set of observations. (This will provide slight relief to the hospital staff, good relationships with them should be established.) For the control group (CMC), the trained nurses will not provide routine care, but they will perform the same set of standard observations, so that the actual doing of the observations will not affect the outcome (Hawthorne effect). Should they however make observations requiring action, they should inform the nurses working, and a note of such action made. It would be acceptable for one nurse to relieve another in observing any infant.

The total time nurse researchers spend physically with the infants should be the same for both groups. This is to ensure that any effects seen are not due merely to a difference in the physical presence of the nurse researcher (the "doula" effect, Kennell et al 1991; Klaus and Kennell 1997). Effects on the mothers cannot be completely excluded because the CMC mothers are separated from their infants. However, effects on mothers is not the object of this study.

Apart from the fact that the newborn is receiving SSC, rather than being in an incubator or cot, the care provided to both groups should be as similar as possible, and the measurements done on them likewise.

Should the neurobehavioural hypothesis hold, some of the SSC will express breastfeeding behaviours. These will be specifically looked for and recorded. However, during the first six hours, breastfeeding instruction should be the same for both groups, and will be provided in a standard format to all mothers of both groups by the nurse researcher. The mother will be assisted to express, and any colostrum or milk produced will be given to the infant. The mother will be given as much information as the nurse researcher feels she can assimilate, and record what information was given. Maternal milk expression efforts and output will be recorded.

Bottle feeding should not be encouraged/allowed in the first six hours, because bottle-feeding is per se stressful, and an un-necessary confounder. Bottles are not used at Groote Schuur, though they are used at the other hospitals.

Some of these infants would be kept nil per mouth for 24 hours in the control group, in the SSC such an instruction should NOT be made unless clinically indicated.

For both groups, routine care procedures must be the same. Chloramphenicol eye ointment is routinely given in the as part of the delivery routine, as is vitamin K injections.

BCG and polio vaccinations are given before discharge.

Certain procedures are to be avoided in the first six hours: there will be no gastric suctions performed, and no baths done. The routine placing of intravenous fluids should be replaced by a judicious approach - in which the decision is based on the observations provided by the nurse researcher, with the criteria for the decision made explicit and recorded by the nurse researcher. A minor hypothesis is that fewer drips will be required if more breastfeeding is established. BCG and oral polio vaccine will be given on discharge, and never before 6 hours.

Routine observations - 6 hourly for larger and stable newborns, more frequently for smaller and potentially unstable: temperature, pulse rate, respiratory rate, oxygen saturation, dextrostix, observed for retraction, grunting, colour and apnoea.

Study observations - see separate chart, (Appendix 6 and 7) from birth to hour, 6, and hour 6 to day 3.

For both groups, "bail-out" points to be specified on the basis of the observations made, for transfer to NICU or for high care. These are already defined for the units. Precise details of incidents will be collected for each such incident.

Oxygen therapy to be provided if necessary, its requirement is not per se reason for bailout. For both groups, treatment interventions as required based on observation and monitoring should be the same, and recorded as to time, intensity, frequency as appropriate. On recovery, infants should return to the original group allocated.
Observations are to be recorded as per standard record for both groups, with additional information being recorded as per observations made of behaviour.

The initial 6 hours will be the intensive phase of observations for research data, for which the study will provide "nurse-power". At end of this time, nurse researcher, ward nurse and neonatologist on duty are to make decision on continued care, depending on preparedness and willingness of mother, state of baby, state of ward, availability of staff, etc. Nurse researcher should do an "interim interview" with mother and complete the data set.

Routine observations made after 6 hours will form the basis of subsequent research data, but will not have the status of randomised control trial, though may be valuable for descriptive purposes. The four nurse researchers should monitor the quality of these for both groups, and extract the required data from the patient files at the set times and days. Data on time spent on SSC may have to be subjective in relying on mother's feedback, if nurses unable to provide constant surveillance.

After the initial six hours, routine care of infants in either group will not be influenced in any way by the nurse researcher, whose sole task will be to gather information.

Mothers should be allowed to practice SSC continuously. Should the mothers wish to do so, beds in, or contiguous to or adjacent to the neonatal nursery will be required, (Mowbray Maternity already have such, Groote Schuur has beds nearby, Somerset does not at present). Even while doing continuous SSC, they may wish to be relieved for short periods, and for such purpose, incubators or cots should be available. Actual times spent in any method to be documented. For continuous care, mothers need to be ambulant, and for that the baby should be assessed as stable. For ambulant care, some means of supporting the babies weight below the mothers chest and the babies buttocks is required, any means found comfortable for the mother is acceptable. (The initial securing by the cotton cloth is for reclining care, baby is secured "horizontally" to the mother, not "vertically".) Fathers may also do SSC on infants.

In the control group, mothers and infants will also be able to KMC after the six hours, as suggested or indicated by normal ward routines. As for the intervention group, this decision is partly the mother's and partly the ward staff's. Exact times spent on SSC for each case will be recorded.

On discharge of the baby, a full set of data will be collected for all mothers and infants in both groups, which will include a questionnaire for the mother. Agreement will be sought that for the SSC infants, discharge of the dyad should not occur before the third day, for CMC infants discharge of the infant should not occur before the third day. Due to severe bed pressure, mother's who are otherwise healthy are discharged the same day, and if their babies are well and near 2000g, they are often discharged before the third day. For the purposes of obtaining comparable data for a second end point, a minimum of three days is needed for both groups.

No subsequent follow-up is planned within the ambit of this trial. Obtaining follow-up data has previously been shown to be extremely difficult, due to the mobile nature of the population, many being resident in the Eastern Cape. Full addresses and contact details will be however be routinely collected.

Pre-randomisation care for both groups:

At birth, the infant is to be delivered on to a four-layered theatre cloth on mother's abdomen/chest, where infant undergoes the following as speedily as practical in defined sequence. This will be done by one of the nurse researchers who can be assisted by a neonatologist or midwife as available/needed.

1 assessed as to need for resuscitation: perform on mother's abdomen/chest
This will include gentle suctioning of the airway, oxygen by mask, bagging. If other resuscitation needed - will require separation, to be noted, return to allocation group if possible.

2 Apgar score 1 min done

3 Baby dried (leave Vernix)

4 Umbilicus tied with string (not clamps !!)

5 Baby weighed naked on scale next to mother's bed.

6 Place naked (sic) on mothers naked chest

7 Cover with pre-warmed double layered cotton cloth

8 Apgar score 5 minutes exclude if less than 6

9 Put bed to 30 degrees (+/- Semi-Fowlers position)

Steps 1 - 9 should be done within 1 - 5 minutes.

Eligibility agreed by nurse researcher and attendant midwife/neonatologist

Randomisation by minimisation method, laptop in delivery ward.

Intervention protocol

Skin-to-skin contact group -

10 Continue with third stage for mother if needed - as per routine, defined

Apgar score 10 minutes.

Monitor probes placed.

Nurse researcher remains with dyad for 6 hours continuously.

When routine midwifery care completed, (5- 20 minutes) infant should (while remaining on mother), receive a small diaper, and a standard cap made out of stockinette. Should bed pressure so dictate, the mother-infant dyad can be moved to any ward or bed available. Such a bed should be in the same room throughout the study, and conditions in that room described. If the room has other beds, mother's randomised to control group should not be nursed in the same room. Extra heating would not be required, other than for the mother's comfort.

In the first 90 minutes, the baby should be allowed freedom of movement, which requires cover with a loose cotton cloth. The infant should be assisted in any movements it attempts, specifically assistance to perform innate breastfeeding behaviours. Recognition of these will be included in the initial teaching of the nurse researchers, and notes of these will be recorded narratively.

After 90 - 120 minutes, the infant should be secured to the mother, by means of a meter square cotton theatre towel folded diagonally in two, round the mother and the baby, secured high in the axilla, in such a way as to fix the head and chest of the infant with the head in a slightly extended position on the mothers chest. The hips should be flexed and extended in "frog position", arms also flexed. In the first six hours the mother should remain at 30 degrees in the bed, short periods being upright for lavatory and food allowed. She should be allowed, even encouraged, to sleep if she wishes. One of the hypothesised effects of SSC is production of CCK (cholecystokinin) causing sedation (Uvnas-Moberg et al 1987); another is behavioural synchronicity (de Chateau and Winberg 1977). In the final hour, if there are infant cues for interaction and breastfeeding attempts, the mother should be awake.

Six hours would be the **primary end point**. Six hours is hypothesised to be the time required to achieve physiological stability, and six hours would allow time for spontaneous breastfeeding, that is mostly likely to happen in the first and final hour.

At this stage an assessment of stability should be made, and a decision made as to the need for further observations, in consultation with the neonatologist on duty or sister-in-charge if indicated. The intensive observations made for the purpose of the study will be replaced by the routine observations indicated by the patient's condition according to ward routines and

protocols. The nurse researcher would therefore be relieved, and hand over formally to the nurse in charge of the unit.

Mother's consent to continued participation may be partial or reserved. Should pressing social reasons or other reasons demand it, temporary or continued care in an incubator or cot must be accepted. Every effort should however be made to give such information to the mothers that they agree to randomisation with the 50% chance of being required to do a minimum of 6 hours of SSC.

Control group care -

At birth, same as for steps 1 to 9 above.

Once randomised to CMC, **the nurse researcher takes observer status only**. The infant is managed and assessed by the neonatologist or attendant midwife. The observations made will include information on the whereabouts of the mother, and all interactions between the mother and the baby. The physiological observations will be provided by the multi-purpose monitor, which will not interfere with routine management.

The first 20 minutes of care is provided by midwives in the labour ward, babies are subsequently handed over to neonatal units. This will mean full information of the RCT to both sets of nurses, as the period being studied overlaps two "jurisdictions". The nurse researcher will make observations and record time of transfer and handover, she will remain with the baby for the full six hours. (The nurse researchers will be providing the care to the SSC babies throughout.)

Observations will be the same as for SSC group - see separate sheet (Appendix 6 and 7).

As clinically indicated and as per current routines, milk, formula, fluids can be given by NGT, by spoon or cup, or IV, all to be documented.

Comments on biases

selection bias - There will be some possibility of bias, in that infants born before arrival or in the MOU's may represent a different category of patient's with different prognosis. Conclusions of this trial would therefore need to be tested in the setting of the MOU before any generalisation is completely valid.

performance bias - blinding will not be possible. Contamination problems will need to be guarded against, and the nurse researchers will be given specific instructions and guidance with regard to such, and recording problems.

Having four nurse researchers could result in some performance bias, but that bias would be spread to both groups equally. Care will need to be taken that nurse researchers are not responsible for contamination in mixing methods of care. There will be some bias in that the control group will receive extra observations, more than the CMC would normally. This would bias results in favour of the control group, and would make the CMC in the trial period not accurately comparable with the real CMC. This compromise is ethically motivated. In sophisticated centres, ethics committees approve intense observations with "screens blinded" the data being collected electronically and analysed subsequently. Such technology is not available.

attrition bias minor protocol deviations are likely in the light of two hospitals being used, but in view of this being a management trial, such deviations should not be cause for exclusion. Care will be taken there is no loss of records or data. Any mortality will not be part of attrition but part of the set. For the main outcome measures, no attrition is anticipated.

detection bias - in view of the two hospitals and four nurses this can be anticipated. However, the measures being taken are standard and routine, measured by the same instruments, and fairly objective. The nurse researchers will have as part of their functions the responsibility of verifying and validating data, and standardising equipment used.

generalisability - exclusions are based primarily on mothers in this trial, with the particular intention that any conclusion regarding the safety of KMC should be generalisable with regard to the infant. Analysis of data will regard subgroups of infants with regard to weight categories and gestational age categories (as per framework), with particular attention to the lower weights and ages. The context cannot readily be generalisable, but a positive outcome in this context will provide support and impetus for a similar RCT in a more disadvantaged context, and in smaller and more premature infants.

Measure intervals

As above, the end of 6 hours is the first end point, and the most important.

The second end point will be at three days, which for some will coincide with discharge, for those discharged later, the final end point will be the day of discharge.

To have the endpoint at "ready for discharge" can make comparisons technically difficult. It should be noted that SSC makes mothers more competent and therefore both willing and able to take their babies home earlier. If the same policy of "ready for discharge" could be unbiasedly applied to both groups, the discharge weight and discharge PCA (post conceptional age) could be compared. As ready for discharge cannot readily be quantified, an objective weight is preferable. This may require prolonged stays and unnecessarily disrupt services. Therefore, three days will be taken as the objective comparative standard, with infants staying longer being measured at discharge.

Main Outcome measures

1 ***Number of NICU and high care admissions within first six hours***

Stabilisation at 6 hours :

2 oxygen saturation recorded, adjusted for oxygen saturation provided/required.

Episodes of apnoea longer than 10 seconds

3 Heart rate

4 episodes of hypothermia, infants experiencing hypothermia

episodes of hyperthermia, infants experiencing hyperthermia

5 episodes of hypoglycaemia, infants experiencing hypoglycaemia

6 composite stabilisation score (SCRIP, see below)

On discharge

7 episodes of complications, infants experiencing complications, nature of complications,

costing of complications

Fischer et al (1998) have developed a "**S**tability of the **C**ardio-**R**espiratory system **I**n **P**reterm infants" (SCRIP) score. The heart rate, respiration and oxygen saturation is monitored continuously during a five minute period, and scores allocated according to the following table.

Table 9 "Stability of the Cardio-Respiratory system In Preterm infants"

	2	1	0
Heart rate	Regular	Deceleration to 80-100	Rate ,80 or >200 bpm
Respiratory rate	Regular	Apnoea <10s, or periodic breathing	Apnoea >10s Tachypnoea >80 pm
Oxygen saturation	Regular >87%	Any fall to 80 – 87%	Any fall below 80%

For a five minute period, each of the three scores are added. The values of the original score have been modified in this table to suit current local practice in the setting units.

In this measure, 4 periods of 5 minutes each will be monitored between the 5th and 6th hour after birth, giving a maximum possible SCRIP score of 24. The end point composite stabilisation score will be this number. It will need to be stratified with respect to KMC infants bailed out to high care or NICU care.

Table 10 Definitions of main outcome indicators

Hypo-thesis	Description in brief	Description	Definition
H1	**NICU 6h**	At 6h: fewer high care /NICU admissions	Any removal from CMC or KMC to high care or NICU
H2a	**Ox sats**	Oxygen saturation better with KMC	Actual levels of O2 measured at hourly intervals
H2b	**Apnoea inf'**	Fewer infants with apnoea in KMC	Proportion of infants experiencing apnoeas >10 sec
	Apnoea #	fewer apnoeas per infant in KMC	Number of apnoeas >10 seconds in whole group per total infants in group
H3	**HR**	Heart rate lower in KMC	Heart rate beats per minute (bpm) at hourly intervals
H4a	**Hypotherm'**	Fewer episodes "hypothermia" KMC	Temperature less than 36.0 Celsius, requiring warming
H4b	**Hypertherm'**	Fewer episodes "hyperthermia" KMC	Temperature more than 37.0 C requiring cooling
H5	**Hypoglyc'**	Fewer cases hypoglycaemia KMC	Blood sugar levels below 2.5 mmol/l at 3 or 6 hrs
H6	**SCRIP**	Composite SCRIP score better KMC	Total SCRIP scores over 4 periods in 5th to 6th hour
			Mean SCRIP score in 5th to 6th hour
H7	**Complic' 3d**	Fewer complications at discharge	Total number of complications requiring HC or NICU

Note that the definitions for hypothermia and hyperthermia here are operational rather than diagnostic, for example, hypothermia is defined at below 35.0 Celsius, which should never happen in this setting.

Other outcome measures

Breastfeeding history and ability should be accurately documented on discharge, whether spontaneous or helped, and other feeds. The LATCH score (Durand et al 1997) will be used in assessing breastfeeding ability.

Table 11 The LATCH score for assessing breastfeeding

		0	1	2
L	Latch	No latch achieved	Holds nipple	Grasps breast tongue down
A	Audible swallow	None	A few on stimulation	Spontaneous
T	Type of nipple	Inverted	Flat	Everted
C	Comfort breast	Severe discomfort	Mild moderate discomfort	Soft and mild tender
H	Hold (position)	Full assist by staff	Minimal assist	No assist from staff

Weight losses and weight gains will be documented, and for total patient days per infant discharged later than three days.

Costing of care per mother and infant from both groups will be done, based on a "case cost" approach for complications, in addition to day costs for routine care.

Mother's feelings and attitudes will be explored by means of questionnaire, based on findings in available research literature.

Data to be collected

The data collection forms will be pre-tested before finalisation on approximately 4 KMC and 4 CMC infants before the trial begins properly (small pilot study).

In addition to outcome measures, background measures will be collected as per forms.

See appendices 4, 5, 6 and 7 for the full data set.

Instruments

Monitoring equipment will include multipurpose modern monitoring equipment, two of which will have to be purchased, (one for each hospital) due to inadequate supply for routine care.

Table 12 Instruments

Hypo-thesis	Description	Indicator	Instrument
H1	NICU 6h	Events	Records
H2a	Ox sats	Oxygen saturation	HP Viridia M3
H2b	Apnoea inf'	Number of infants experiencing apnoea	HP Viridia M3
	Apnoea #	Number of apnoeas among all infants	HP Viridia M3
H3	HR	Heart Rate	HP Viridia M3
H4a	Hypotherm'	Temperature	HP Viridia M3
H4b	Hypertherm'	Temperature	HP Viridia M3
H5	Hypoglyc'	Blood glucose level	Glucometer
H6	SCRIP	Score as defined (total number)	HP Viridia M3 add
		Score as defined (mean per period)	HP Viridia M3
H7	Complic' 3d	Events	Records

Initially these would both be at Mowbray Maternity Hospital, where the majority of infants are expected. Should there be two infants being studied at the same time, (possible in the event of twins), two research nurses should be present. Later if recruitment is necessary from the second hospital, one monitor will need to move there, and may need to be borrowed back in the case of twins. In the rarely expected occurrence of three babies being monitored at the same time, one could be borrowed from the hospital concerned. At worst lack of monitors and or research nurses may result in some loss of subjects, to be noted.

Glucometers should be standardised daily.

Data collection procedure

Forms will be prepared for the randomisation of mothers (appendix 4 page 1), which will ensure that informed consent is obtained, and that all required information is available before delivery. The same form will have the final data required from the newborn determining eligibility. These forms will be in the laptop computer as well as available as hard copy.

Once randomised, a data collection matrix will be followed, (Appendix 6 and 7) and a form tailored to this filled in. In addition, for randomised infants in both groups, a complete set of background and care details will be filled in by the nurse researchers.

On discharge a final data set will be collected by the nurse researcher, which will include a questionnaire on the mother's perceptions of care, experiences and attitudes.

Quality control

The forms collected will be checked by the principal investigator on a regular basis. Details relating to measurement error, reliability, validity will be checked, and corrections and additions made where possible. For the period prior to discharge, data can be expected to be incomplete, but for the primary end point no attrition should be expected.

Data management

The data will be entered into Microsoft Access, using a form with preset minimum and maximum values and internal validity rules. For the subsequent analysis, required data will be exported to Microsoft Excel, for preliminary inspection visually and subsequent statistical analysis.
Statistical advice and assistance will be sought through the MRC, and from Gene Anderson.

Data analysis

Data analysis will be done ongoing.

The following table presents the statistical tests to be applied. The use of a 2 tailed t test will allow the differentiation of "no difference" from a superior or inferior result of the intervention.

Table 13 Statistical tests

Hypo-thesis	Description	Measures	Data type	statistical test
H1	NICU 6h	proportion	discrete	Fishers exact test
H2a	Ox sats	mean & SD	continuous	Students t test
H2b	Apnoea inf'	proportion	discrete	Fishers exact test
	Apnoea #	mean & SD	continuous	Students t test
H3	HR	mean & SD	continuous	Students t test
H4a	Hypotherm'	proportion	discrete	Fishers exact test
H4b	Hypertherm'	proportion	discrete	Fishers exact test
H5	Hypoglyc'	proportion	discrete	Fishers exact test
H6	SCRIP	number	rank ordinal	Wilcoxon 2 sample test
		mean & SD	continuous	Students t test
H7	Complic' 3d	proportion	discrete	Fishers exact test

For other outcomes, appropriate statistical analysis will be used, recognising that care after 6 hours will not be uniform in the groups, and are not the main focus of this trial.

The budget and feasibility sets the sample size for each group at 50. In the following table, rough estimates have been made of the expected results in each group, and the "Sample size req'd" (required) to demonstrate that difference calculated. This is based on a formula for a two sample, two tailed t-test with an alpha level of 0.05 (p value) and a power of 0.80. The sample sizes required for some of the hypotheses are larger than planned, but given the approximate estimations, and the hypothesised effects of the intervention, a sample size of 50 in each group is justifiable.

The final column "Detectable" shows the smallest difference that would be required between the two groups of 50 subjects for there to be a statistically significant difference (p 0.05).

Table 14 Statistical parameters

Hypo-thesis	Description	Statistical test	Expected for CMC	Expected for KMC	Sample size req'd	Detectable
H1	NICU 6h	Fishers exact test	15/50	5/50	64	11 cases
H2a	Ox sats	Students t test	90 +/- 8	92 +/- 3	100	3.11 %
H2b	Apnoea inf'	Fishers exact test	10/50	3/50	92	9.5 cases
	Apnoea #	Students t test	.06 +/- 0.05	0.02 +/- .02	25	0.02 /infant
H3	HR	Students t test	140 +/- 15	150 +/- 10	23	7 bpm
H4a	Hypotherm'	Fishers exact test	6/50	1/50	104	7.2 cases
H4b	Hypertherm'	Fishers exact test	2/50	0/50	196	3.96 cases
H5	Hypoglyc'	Fishers exact test	4/50	1/50	211	6.2 cases
H6	SCRIP	Wilcoxon 2 sample	16 +/-6	20 +/- 4	25	3 units
		Students t test	4 +/- 1.5	5 +/- 1	25	0.71 units
H7	Complic' 3d	Fishers exact test	20/50	7/50	47	12.5 cases

ETHICAL CONSIDERATIONS

The protocol will be prepared in a manner as to be presented to the Groote Schuur Hospital/University of Cape Town Ethics Committee, within whose sphere of authority the research is most likely to be carried out. A three page form has been obtained.

EXPECTED OUTCOMES (advantages)

In view of the literature reviewed above, it is expected that the profound and considerable advantages shown with SSC applied late and to big babies will be shown to be present when applied from birth to small babies. From the theoretical and anthropological point of view, the expected outcome of KMC should be superior to that of CMC. There is support for this from a non-RCT study of birth KMC reported (Bergman & Jurisoo 1994).

In particular, it is expected that there will be fewer complications and admissions to high care and the NICU, and that there will be improved breastfeeding rates.

References: (see main list below)

PROJECT MANAGEMENT

Principal investigator

Nils Bergman		University of the Western Cape / PAWC

Collaborators

Lucy Linley	Co-investigator	MMH neonatologist
Sue Fawcus	Co-investigator	MMH obstetrician
Mary Hann	Co-Investigator	GSH neonatologist
Gene Anderson	Co-investigator	Case Western Reserve University

Consultants

Atties Malan	University of Cape Town
Dave Woods	PMNS / UCT neonatologist
Adriano Cattaneo	BURLO, Trieste/WHO

wwww	Nurse researcher
xxxxx	Nurse researcher

yyyyy Nurse researcher

zzzzzz Nurse researcher

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Chief Nursing Services Manager, Groote Schuur Hospital & Mowbray Maternity, Ms Thomas.

Dr John Frankish, Regional Director, Metropole, Provincial Administration: Western Cape.

Prof David Sanders & Dr Mickey Chopra, Public Health Programme, University of the Western Cape.

Mr Carl Lombard, Statistician, CERSA (Biostatistics), Medical Research Council, Tygerberg 7505.

PROBLEMS ANTICIPATED

Funding will be required

Nurse researchers will require both NICU experience and some research experience, and would be required to work odd and long hours, for a contract period; there may be problems in identifying such.

Nurse researchers will have to coordinate with fulltime staff in the hospitals, both in obstetric and neonatal units.

BUDGET

Table 15 Budget (version as at 980111)

All of the nurse researchers will be doing time, which will be compensated at a flat rate calculated just above the hourly pay of a CPN, = R40 per hour.

	Item	Reasoning	Rand cost
Personnel	Project coordinator	1 hour per day x R40 x 5d x 52wks	10400
	Project coordinator	2 x 2wks full pay	20000
	Four nurse coordinators	Training/meeting 10days x 8 x 40	12800
	Four nurse coordinators	Ward familiarisation 1wk x 40hrs	6400
	Four nurse coordinators	Ward presence 8wks x 40 hrs	12800
	Four nurse coordinators	100 infants fail eligibility x 2h xR40	8000
	Four nurse coordinators	100 infants x 8 hrs per infant x R40	32000
	Four nurse coordinators	Follow 100 inf x 6hrs each x R40	24000
	Statistician	5 separate days (5 x 8 x 40)	1600
Training and Meetings	Workshop initial	2hosp x (8 PNs, 4drs,3etc) @R50	1500
	Reports /progress review	10 people @ R50 x 5 meetings	25000
	Workshop final	50 people @ R60	3000
Travel	Nurse researchers	100 visits x 10km x R1	1000
	Visit Anderson	1 x USA return + bits	16000
Equipment	HP Viridia M3	x 2 (for all stabilisation measures)	100000
Administration	Pagers for nurse researchers	4 x 400	1600
	Randomisation computers	Laptop (randomisation, data collection)	6000
	Main project computer	Up to speed laptop + printer	12000
	Stationary	various	4000
Subtotal			298100
Unforeseen	includes inflation	15%	44715
TOTAL			342815
	Exchange rate 6.0	(October 1998)	
	US Dollar cost	**$**	**57135**

Budget justification

Costs of care as per normal service delivery, not included here. Care for these infants would in any way be included in the budgets of the hospitals. The trial would in fact relieve the normal "on-duty nurses" of a little of their work, freeing them to attend more to other sick infants in the units.

90% of the funding will be required at the beginning of the project, for equipment and data collection, after data collection the remaining 10% will be required.

Apart from equipment, the main cost will be the nurses. At the beginning of the project it is vital that they familiarise themselves with the units in which they will be doing research, and that they establish cordial relationships with the fulltime normal staff. Time (=funding) is set aside for this process. This time will also be used to provide education to referral units on the trial, to speak to mothers at antenatal clinics, and inform referral hospitals and units of the trial. This initial period will be continuous, after that the work of the nurse researchers will be primarily as required only, they will be on call, but will be paid per hour of actual work done.

Should any funds be left over at the end of the project, they could be used to buy monitoring equipment for the hospitals participating. The two monitors will be donated to the units as a token of appreciation for assisting with the study.

The University of Cape Town has facilities and routines for administering funds donated for research.

DURATION

This will depend on when funding is assured. Taking funding secured as starting point

Month 0	Funding
Month 1	Recruit nurses (suitable candidates are known by the hospitals)
Month 2	Training of nurses, preparation, piloting of forms and protocol details
Month 3	Data collection allow 9 months (could be 3 if other sites refer)
Month 12	Data collation, analysis
Month 15	Preliminary report
Month 18	Final Report

APPENDICES

Appendix 3	Mothers consent form
Appendix 4	Data collection tool - information on mothers
Appendix 5	Data collection tool - information on infants
Appendix 6	Data collection form first 6 hours
Appendix 7	Data collection form first 3 days

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Code: One star (*) indicates article referring to KMC

Two stars (**) indicates article critically appraised in systematic review (SECTION TWO)

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Appendix 1
Outline of a Cochrane Review.
(electronically extracted from the Cochrane Collaboration Handbook)

Each review consists of:

a cover sheet - giving the title, citation details and contact addresses
an abstract - using a structured format
the text of the review - consisting of an introduction (background and objective), materials (selection criteria and search strategy) and methods, results (description of studies, methodological quality, and results), discussion and conclusions.
standard tables and figures - showing characteristics of the included studies, specification of the interventions that were compared, the results of the included studies, and a log of the studies that were excluded.
references

Standard headings and tables guide reviewers preparing a report and make it easier for readers to identify information that is of particular interest to them. The headings are listed below. The content that should follow each heading is described in the appendix attached to this section (Guide to the format of a Cochrane Review).

Outline of a Cochrane Review
Cover sheet:

Title
Short title
Reviewer(s)
Contact address
Name
Organisation and address
Telephone number
Facsimile number
E-mail
Date last edited
Date of last substantive update
Sources of support to the review

Abstract

Objectives
Search strategy
Selection criteria
Data collection & analysis
Main results
Conclusions

Text

Background
Objectives
Selection criteria
Types of studies
Types of participants
Types of interventions
Types of outcome measures
Search strategy

Methods
Description of studies
Methodological quality
Results
Discussion
Conclusions
Implications for practice
Implications for research
Acknowledgements
Conflicts of interest

Tables and figures:

Table of comparisons
Table of included studies
Table of excluded studies
Data tables and graphs

References:

References to studies
Studies included in this review
Studies excluded from this review
Studies awaiting assessment
Ongoing studies
Other references
Additional references
Previously published versions of this review

A full Cochrane Review usually takes between 12 and 18 months to complete. Though a final report is submitted, a Cochrane review is generally ongoing. As more research on the subject is found, "substantive updates" are done. The abstract of any review is to be found free on the Internet.

Appendix 2
Table of articles analysed.

To include	No, BWt, BGA, other	duration days, duration in day Wt & PCA started,	SSC compared to?	Food and feeding Respiration, morbidity.	Measure + Result with p value of NS		
Author Date	**Participants**	**Intervention SSC**	**Control condition**	**Fixed variables**	**Outcome measures**	**Comments & flaws**	**Notes**
RANDOMISED o	**CONTROLLED**	**CLINICAL**	**TRIALS**				
Blaymore 1996	25:25 Wt <1500 Ma intend to BF Bwt 993:942 BGA 28:27	SSC for 10 min for 10 days started 29:30 d and GA 32:31	wrapped in blankets in mother's arms	No respiratory problems or help prior morbidity equal and groups ISQ	BM vol - NS incr, dura' - incr 0.01 HR - ISQ NS RR - ISQ NS Temp - ISQ NS Ox - inc 2% 0.001	3643 admit <1500 only 78 intended only 50 agreed. Once on - tight Effect from small intervention selexn - B perform - A attrition - A - detexn - A bias rating - B	All info there. BF duration firm Oxygen saturation firm
Anderson 1998	42:45 Wt? GA? but 'normal healthy'	SR selfregulatory started 30 min given until 6hrs	NR nursery routi started 60 min for 6 hours	Feeding not described	Sal cortisol at 6hrs - lower 0.05 (4.0 vs 8.9)	effect of feeding uncontrolled selexn - A perform - B attrition - B detexn - A bias rating - B +	Brief resarch report. Separation firm
Charpak 1997	382:364 after icu only, 1084 started, 160 died, other excl', 131 refer away Mothers bias - had to agree 1 yr, could exclude in favour of KMC	KMC discharged, any wt/GA 24 hours / day strict upright daily visits supplements	minimal care unit incubator D/C 1700g restrict access daily visits supplements	EBF:PBF ISQ 46%:48% ?not described prior to random' and not described for control, only "approp' wt gain"	mortality - ISQ 6:10 NS infxs - sev decr 2.8:6.7% 0.019 hosp days - decr by 1.1 d overall but more for <wt readmission ISQ growth - ISQ feeding - ISQ	90% at PCA 40 :(Mothers bias "none refused" - but bias came in before the offer Control care "old" 11% K no comply some KMC stayed Normal feeding routines bottle vs breast and BM vs form' not shown selexn - A perform - C attrition - B detexn - A bias rating - C	HPNMR 70/1000, very high. Kangaroo nutrition not much part of the scheme, and not integrated into the care. Bias rating - SSC cannot be evaluated due to early D/C and BF differences.

Christensson 1992	25:25 fullterm healthy	started at birth, (actually 8-10 m) lasted 90 minutes 3385g, term	cot after initial care on ma abdomen	baby not moved baby not fed during 90 min	temp- incr 0.01 HR - ISQ NS RR -44:49 0.05 color - ISQ blood gas - DiffBE 3.4:1.8 0.05 blood gluc 90 m - 57.6:46.6 0.05 Crying - episodes 4:41 time 70:2939	Feeding was not allowed, but would otherwise occur normally. selexn - A - elig? perform - A attrition - A detexn - A bias rating - A	No major flaws crying firm more rapid meta-bolic adaptation Temp firm Emphasis on "anti-separation"
Christensson 1995	15:14 (15both) 39.6 weeks 3214g	started at birth (actually 4-12 m) 90 minutes	cot 3rd gp: 45m from cot to mother	no pain relief IP no moving	temp - incr 0.03 crying- dec 0.001 CCK - ISQ NS oxytocin ISQ NS	Feeding was discouraged - part of innate agenda first hour. selexn - A - perform - A attrition - A detexn - A bias rating - A	tight crying firm
Durand 1997	? (tables missing) term 2895-4365 g	started 30 minute lasted 2 hours B/Feeding started	radiant heat 30m two hours fed15ml formula & 15ml glucose	no bathing	temp - better NS Gluc - decr 0.01, but within N All SSC BF successfully and without help	Concl = SSC safe BF better selexn - C perform - B attrition - A detexn - A bias rating - C	Two comp of KMC Study doesn't tease out difference - ?SSC + form&gluc ?Cot + EBM 30ml
Johansson 1992	98:100:99 SSC:oil:plastic Any wt/age 66% of all deliv	"immediate" after drying	rubbing with mustard oil swaddling in plastic		Temp - all ISQ NS	Feeding not described selexn - A perform - B attrition - A detexn - A bias rating - B+	SSC safe for temp even in Nepal!
Kambarami 1998	37:37 Less than 7days Bwt 1460:1400	BF entirely upright position started day 5:3 SWt 1390:1320g 24 hours a day	incubators (cots) formula or BM or both	All vetted no resp problems etc before entry	Wt/gain - incr 20.5:10.5 0.001 morbid hosp dec 16.4:33.2% 0.007 ALOS - dec 10:25d 0.001 survival - incr 37:34 Mortality 0:9%	GA not recorded not random - alternate - was some room to predict. Feeding of control not standardised- could be cause for difference found, rather than SSC selexn - D perform - B attrition - A detexn - A bias rating - C	Third world patient centred outcomes PCO

Kronson 1996	14:14 1338:1335g 31.8:32.5 wk	1.9 hours per day daily till D/C 1500g 19d old	incubators 0.1 hrs SSC 2 patients once 1510g 17d	Feeding policy same, routines same for 22 hours	Wtgain/d - incr 27.7: 24.3 0.05 length - NS cranial - NS ALOS - decr 14.5:17 0.05 BFRD - incr 100:71% 0.05 BFR2 - incr 93:57% 0.05 qualitative - impr ma & staff	not true random - dependent on mothers choice to spend time - CCT. (3 did decline) selexn - D perform - A attrition - A detexn - A bias rating - B	Daily weight gain firm BFR firm
Michelsson 1996	12:9 fullterm healthy	birth SSC (actually 5 - 14m) lasted 90 minutes	cot 90min	no drug IP	cry signals - dec 48:462 cry type-pain cry - hunger cry - separation distress	RCT info on feeding unclear selexn - B perform - B attrition - A detexn - A bias rating - B	separation suggestive cause stress cry more firm but SEP
Sloan 1994	140:160 1704:1704g 34.6:34.1	SSC upright PCA 12.4d	incubator or crib 13.7 d	BF, hygiene, obs EBF strong both	160 variables !!! severe illness-dec 7:27 0.002 LRTI - dec 6:19 0.02 Readm 4:11 0.13 Costs - decr +/- 220:580 Mortality ISQ NS 11:13 NS	study terminated due to this 85% died before eligibility selexn - A perform - A attrition - B detexn - A bias rating - B-	statistically impressive but some loss in ... firm for dec morbidity firm for costs
Swinth 1998	10:10 and 10 30-35 GA Wt ?	SSC 1 hour + FO, BL for 23 hours 5 -6 days doing phototherapy	Banked light 24h Fibreoptic 1 hour and 23 hrs BL	Not stated	BR - essentially all the same...	Feeding not mentioned selexn - A perform - B attrition - A detexn - A bias rating - B+	Phototherapy during SSC safe, nil contributed
Syfrett 1993	4:4 34-36 wks AGA	SSC 30 minutes 84% of time SSC for 47 hours GA35 2326	SSC 30 - to cot 60 GA 34.5 2288g	Ma desire BF no resp supp	temp - warm 0.05 BF x/d 2:12 0.05 Supp ml 0:62ml Wt loss ISQ ALOS 3.8:14.5 NICU 0%:75%	Pilot RCT morbidity suggest selexn - C perform - C attrition - A detexn - A bias rating - C	followup shows less morbidity ..

Whitelaw 1988	35:36 29.1:29.5 1152:1135	SSC 0.6hrs/day (0-1.5h) 16d (1 - 66d) 1152g (560-1500)	Cuddled in blanket 1.4h/d 1135 (630-1500)		ALOS 30:37 temp ISQ psyc scale ISQ crying 25:38 0.04 BFdur 9.2:5.1 .01 BF>6w 55:28% .02	2:2 died Psyc same, but advanced support in other ways Varia' controlled selexn - A perform - A attrition - A detexn - A bias rating - A	Very little SSC still effects on BFR

INTERRUPTED	**TIME SERIES**	**(REPEATED**	**MEASURES)**				
Acolet 1989	14=14 1060g (0.6-1.43) 28 weeks (25-31) SPCA 35d (6-134) SWt 1550 (1-2.2)	SSC at 60deg 5 +10 minutes	cot prone horiz 5 + 10 min	did include resp' supported babies	PO2, ISQ in N PO2 in lung dis 9.7:8.6 0.01 HR 158:152 .01 Temp warmer NS	3 smalls (1 1.1 1.25) did best! Control for feeding - short spans maybe ok but bottle effect? ?first arm random selexn - B perform - B attrition - A detexn - A bias rating - B	small but suggestive "safe" - firm
Bauer 1997	22=22 <1500g <7days	SSC 1 hr	incubator 1hr		temp rectal incr 0.2C 0.01 temp skin incr 0.6C 0.01 O2cons NS 5.8:6.1	selexn - perform - attrition - detexn - bias rating -	

Bosque 1995	8=8 >1250g AGA	SSC 4hrs/d 6 days /wk 3 weeks	incubator		Apnoea NS bradyc NS O2 desat NS HR NS RR NS Sleep active less 8.9:31.5 .002 Trans sleep more 61:36 .009 Temp decr (0.03) Ma skin temp > incub temp	gavage or bottle given ad hoc - not controlled for :(all 8 did suckle Was noted as a finding: bradycardia episodes more with bottle and gavage, less BF noted - independent of care inc or SSC selexn - B perform - B attrition - A detexn - A bias rating - B+	Valuable finding re problems of feeding method no hats - cause of low temp
de Leeuw 1991	8=8 GA 28 27-29.6 1.1kg 770 - 1465 start day 6-33 all on CPAP	SSC 1 hr 18.1 days old	NICU incub	all unstable on Rx all on TPN and then gavage, same	HR NS (inc bra) RR NS PO2 NS behav state NS breath pattern NS but 3SSC inc reg apnoeas NS temp stable	Safe - firm but note for very small and unstable babies selexn - A perform - A attrition - A detexn - A bias rating - A	
Fischer 1998 not published yet	20=20 no O2 GA 29 (25-32) w Bwt 490-1570 SWt 760-1610	SSC 2 hrs age 23d (5-62)	pretest - test - posttest incub horizontal supine	feeding not defined	HR NS RR NS O2 NS pneumograms ?? SCRIP score NS	Mother self chosen position position varied... flexion bad SSC safe selexn - A perform - B attrition - A detexn - A bias rating - B	Boys less stable than girls
Legault 1995	71 -- 61=61 >7d 1000-1800g stable 5d	SSC 30 minutes 28.6d (7-61) 1225 (685-1835) 30 (24-35) SWt 1407 (1-1.8)	blanket in arms	1hr after oral feed	HR = NS (but bradyc 1:4 epis) RR = NS (but resp pauses 4:14) O2 - incr 0.0001 Temp rose = NS ma satisfaction NS ma pref SSC 73.8%	mother chose time 2nd test 1d to 7d later too long:(blanket gp had desats before 30m selexn - A perform - B attrition - B detexn - A bias rating - B	showed old removal method to unsafe!

Ludington 1990	8=8 34-36 GA Bw 1475-2765 4M 4F	SSC -inter feed once age 9.5d (2 - 28) Swt 1865- 2560 mother sitting upright, self chosen position	open-air cribs (little detail)	fed every 3 hrs -feeding method? bottle or breast But own control would mean ISQ	HR incr 148:156 Activity decr behaviour state - more quiet sleep	selection bias NA perform bias B attrition A detection A A	firm on state SEP simplistic energy exp eq'n - GIT hormones give more growth with same calories - less calories better used to give more growth.
Ludington-Hoe 1991	12=12 preD/C GA 34.5 Wt 2129 (1.4-2.7)	SSC upright sitting 1.5-2.75 h Age 9.9d (2-28) Swt 2148 (1.8-2.6	clothed, cap, 2blankets in open air crips	BF allowed -none initiated Staff administer feed - ?how	HR - incr9bpm RR - incr 3bpm Ox sat Temp incr	selexn - NR B perform unclear B attrition A detection B	Firm on safe
Ludington-Hoe 1994a	11:13 32-36 AGA	SSC upright GA 34 2062g	incubator naked GA 34 2085g	"feeding" not described bottles taken for granted.	HR inc 144:152 T inc 36.3 - 36.9C Osats dec 94:95% Pneumograms - no periodic breath' stabler HR Sleep - incr quiet regul 9.5-19-7%, decr time active, quickertransition	selexn A performB attritionA detectionA should be safe	firm on safe, sleep better
Ludington-Hoe 1994b	3:3 alternating Bwt 1770:1975 GA 32:33	KC 3 hours 1770g Age 14	control 1975g Age 11	"feeding" not described ? method ? what bottles accepted	HR incr Temp incr Apnea fewer KC Less periodic bre' Inc quietreg sleep	selection D perform B attritionA detectionA validity short coming noted by authors	small and sick seems ok but doubtful
Messmer 1997	20=20 26-37 bw 750-1500	SSC 1 hr x 4 upright 28wks PCA 30w Swt 1315 (?SD/range)	incubator prone 30 degrees	NPO IV, gavage breast or bottle feeding every 2-3 hrs "if BF, expressed	Quiet sleep inc 13.6-25.6-15% HR, RR O2 ISQ	20 out of 30, voluntary parents 9 fell out internal exlcusion if drop in temp on KC ?? selection C performanceC attrition C detection A flawed	though flawed, appears safe for babies around 1300g.
Mooncey 1997	15=15 GA 31 (25-33) Bwt 1420 (.5-1.8)	SSC 20min X 1d Age 21d (8-96) Swt 1583 (1.2-2.3	3 inc', 12 crib d1 SSC d2 same time	3 BF, 12 NGT / breast/bottle (bottle stress?), but >30m before	HR RR T ISQ horm 5-10m after cortisol decr 66% 0.008 endorphin dec 74% 0.002	no randomisation sample not def' performance bias BF and position 30-40 vs 60deg blood test techniq influences test - internal validity? but same both gps	The blood sampling before may have been the cause for high level

HISTORICAL	CONTROLS	RETROSPECTIV					
Affonso 1989	33:33	33 SWt 1-30 d GA 31 (26-38)	33 - Matched by convenience GA 31 (26-37)		LOS 41.6:49.4 Ma confidence Inc	Not a trial really, uses a "compare group" for ma's	
Bergman 1994	126	SSC BF birth 1988-93	cots HWB 1994-1987	Essentially - BF same, <100% a/b, oxygen	Mortality impr 10%:50%	allocation total,A performance B attrition A detection B bias - B rating	first article on birth KMC, first mortality
Charpak 1994	162:170	Hospital A SSC started late, were D/C home GA 35 Bwt 1696 Age 9.1 Swt 1610	Hospital B incub GA 35 Bwt 1767 Age 6.1 Swt 1738	Feeding not contr	Survival similar Slower wt gain Query quality, inc devel delay SSC > BF	alloc C perf - C attrition B detection B bias - C rating	problem comparing an intervention which in itself has three interventions ...

Appendix 3
Mothers consent form
(English version, will require translation to Afrikaans and Xhosa in addition)

Dear Ms .....

You are now in labour, and it is very likely that your baby will be born with a much lower birthweight than is normal. This means your baby will not be able to keep himself/herself warm, may not be able to breathe properly, may not be able to feed to begin with, and may be at risk from infections. For these reasons, you are delivering your baby in this hospital, where we will do our best to prevent any problems due to your babies' low birthweight. Usually we do this by keeping baby in an incubator, where we can keep the baby warm all the time, give oxygen if needed, and at the same time keep a close check on your babies' condition. Baby can be fed in different ways depending on how strong he/she is.

However - we are investigating a new method of looking after a new born low birthweight baby, called Kangaroo Mother Care. This has already been shown to be very good and very safe for low birthweight babies when they are a few days old already, even if they are very small. With this method, you will be able to keep your baby with you from the beginning, your own body will keep the baby warm, and your breathing can help the baby's breathing. We can still give oxygen if needed and keep a close check on your baby's condition all the time. With this method, it is also possible even for small babies to breastfeed soon after being born.

We are studying which of the two ways of caring for the baby is best, and we are looking at babies who are more than 1500 grams but less than 2000 grams. For us to be able to do this, we are inviting you and your baby to be part of this study. If you agree, once your baby has been born and weighed and found to be between the above weights, an envelope drawn by chance from a box will decide whether your baby will have the usual care or the new Kangaroo Mother Care. If you agree, a special research nurse will spend the first six hours with you and your baby constantly, whichever group the envelope determines. Baby will have monitoring equipment designed to measure the condition all the time without disturbing the baby. Should anything become a problem, your baby will straight away get the appropriate treatment the hospital is able to give, whichever group he/she is in.

If you agree, and if you are given to the KMC group, you will need to spend a minimum of six hours providing skin-to-skin contact to your baby. Your baby will need to stay at least three days in hospital. You do not have to stay in hospital after the six hours, but a special room will be reserved for you to stay with your baby, and you can do KMC as much as you like to do after the six hours. If you are not allocated to the KMC group, you would not be doing any KMC in the first six hours, but you may do so after this time of you wish.

If you do not want to be part of this investigation, your baby will be given the usual care and the usual observations by the nurses in the ward.

Read by the mother .....

Read to the mother ..... by .....

Date .....

I *agree / do not agree* to be part of this investigation.

Signature: .....

Appendix 4
Data collection tool - information on mothers

KANGAROO MOTHER CARE
DATA COLLECTION TOOL:
INFORMATION ON MOTHERS

Code number .....
Non participant [ ] KMC group [ ] CMC group [ ]

1 DATA ON ALL MOTHERS APPROACHED - PRE-ELIGIBILITY

Hospital folder number:

Age .....
Grav .....
Para .....

Mother eligibility?

Well enough to do SSC	YES NO
HIV status known positive	YES NO
Caesarean section	YES NO
Other ineligible	.....
ELIGIBLE	YES NO
If NO	Subsequent birthweight .....

If eligible - Consent YES NO

If NO
Subsequent birthweight .....
Reason for NO (voluntary) .....

If YES:

Infant eligibility

Apgar >6 1 minute	YES NO
Weight 1500 - 1999g	YES NO
No obvious malformation	YES NO
ELIGIBLE	YES NO
If NO	Subsequent birthweight .....

If YES

RANDOMISE the dyad (sealed envelope)
Mark the allocation with a ring KMC CMC

Infant has own form, both groups
Continue this form for all mothers.

2 INITIAL DATA ON ALL ELIGIBLE MOTHERS

(This information should be filled in within 24 hours of the delivery)

Name of the neonate: .....
Code number of the neonate: [ ]
Gender: M [] F []
Name of the mother: .....
Address: .....
Form completed on: .../.../...
By: ..... Code [ ]

Age of mother (years last birthday): .....
Gravidity
Parity
Race
Number of abortions: .....
Number born alive: .....
Number still alive: .....
Age of the previous child: .....
Number of stillbirths: .....
Number of cesarean sections: .....
Marital status:

1 married []
2 widow []
3 separated []
4 free union []
5 single []

Educational level:

1 mother		2 father
[]	illiterate	[]
[]	literate	[]
[]	primary	[]
[]	intermediate	[]
[]	secondary	[]
[]	university	[]

3 Number of completed years of education?
4 mother ..... 5 father .....

Socioeconomic status:

1 mother		2 father
[]	employed	[]
[]	sporadic employment	[]
[]	unemployed	[]

If employed - details of maternity leave conditions .....
Housing:

1 permanent material []
2 non permanent material []

Number of rooms: .....
Number of permanent residents: .....
Running water: yes [] no []
Toilet or latrine: yes [] no []
Radio: yes [] no []
Television: yes [] no []
Smoking yes [] no []

1 years smoked
2 number per day

Alcohol yes [] no []

1 years used
2 quantity

Date of delivery: .../.../...
Time: ...:...
Place of birth: ..... Code []
Type of delivery (tick one):
normal vaginal []
breech []
forceps []
vacuum []
Drugs/medication given during pregnancy..(what, dose, time)
1 .....
2 .....
3 .....
Birthweight: ..... gr
Gestational age by dates
Gestational age as scored
Classification SGA AGA LGA
Time membranes ruptured (hours)
Amniotic fluid infection syndrome yes [] no []
RPR status Pos [] Neg []
RPR +ve treated [fully] [partially] [late] [not yet]
maternal antenatal complication yes [] no []
specify .....

Are you planning to breastfeed your baby? yes [] no []
Have you breastfed a previous baby? yes [] no []
For how long?

Nurse researcher will qualitatively assess mothers feelings and confidence level.

3A FINAL DATA ON ALL ELIGIBLE MOTHERS (DAY THREE)

All mothers enrolled into the study, **in both groups**, will be interviewed on the 3rd day, which for some will be discharge date.
The same questions should be repeated if the discharge day is later.

Are you happy with the assignment to this group? yes [] no []
Would you prefer to be in the other group? yes [] no []
Why?
Do you feel comfortable here? yes [] no []
Is this method of care convenient for you? yes [] no []
Why?
Do you trust the method of care? yes [] no []
Why?
Do you have some worries about your baby related to the method of care? yes [] no []
Explain:
How is your baby being fed?
1 breastfeeding [ ]
2 expressed breastmilk [ ]
3 formula [ ]
4 mixed [ ]
5 do not know [ ]
Do you think this is the best way to feed your baby? yes [] no []
Why?

Compared to the day your baby was born, do you feel more or less confident in caring for your child?
more [] less []

Why?

Do you feel that you would be able to take care of your baby at home? yes [] no []

Why?

In your opinion, what are the major advantages of the method of care your baby had?

In your opinion, what are the major disadvantages of the method of care your baby had?

Do you think this method of care is easy to apply?
yes [] no []

Why?

Do you feel you have been supported by the staff?
yes [] no []

Why?

How?

Have you been discouraged by the staff? yes [] no []

Why?

How?

Do you feel supported and stimulated by other mothers?
yes [] no []

Why?

How?

Have you been discouraged by other mothers? yes [] no []

Why?

How?

Does your partner agree with this method of care?
yes [] no []

Why?

Does the rest of your family agree with this method of care?
yes [] no []

Why?

Have you any experience of the care you want to talk about?

What are your plans with regard to breastfeeding in future?

3B QUESTIONS TO MOTHERS NOT DISCHARGED

Is it important to stay here with your baby? yes [] no []

Why?

Who is taking care of your other children at home?

1	father	[]
2	grandparents	[]
3	family	[]
4	neighbours	[]
5	others	[]

Can they manage without you? yes [] no []

Why/how?

Does your partner come to visit you? yes [] no []

How often?

Does your family come to visit you? yes [] no []

How often?

3C QUESTIONS TO DISCHARGED MOTHERS ONLY

What is your feeling about being separated from your baby?

How many times a day do you come to the hospital?
(only for mothers who do not stay in the hospital).....
Would you like to spend more time with your baby? yes [] no []
Why?

4 DATA EXTRACTION FROM FOLDERS AND PATIENT NOTES

(For mother only)
Total time spent in hospital on day 1: .....
Total time spent in hospital on day 2: .....
Total time spent in hospital on day 3: .....
Total time spent in hospital over 72 hours: .....

Total time SSC provided to infant on day 1
Total time SSC provided to infant on day 2
Total time SSC provided to infant on day 3
Total time SSC provided to infant over 72 hours

Any maternal antenatal complications?
Any maternal postnatal complications?

Time until fit for routine discharge, from birth, in hours
Time until actually discharged, from birth, in hours

Number of visits by mother
Number of visits by other

Feeding method:
details
Breastfeeding attempts
Any breast problems?

Expressed breast milk volume day 1
Expressed breast milk volume day 2
Expressed breast milk volume day 3

Appendix 5
Data collection tool - information on infants

KANGAROO MOTHER CARE
DATA COLLECTION TOOL:
INFORMATION ON INFANTS

Code number .....
KMC group [ ] CMC group [ ]

1 INITIAL DATA ON ALL ELIGIBLE/RANDOMISED INFANTS

Name of the neonate: .....
Gender: M [] F []
Name of the mother: .....
Address: .....
Form completed on: .../.../...
By: ..... Code []

Date of birth: .../.../...
Time: ...:...
Place of birth: ..... Code []
Type of delivery:
1 normal vaginal []
2 breech []
3 forceps []
4 vacuum []
Birthweight: ..... gr
Apgar 1 minute
Apgar 5 minutes
Apgar 10 minutes
Gestational age by dates
Gestational age as scored
Classification SGA AGA LGA

Resuscitation needed? yes [] no []
If yes, specify (tick as appropriate):
1 stimulation []
2 aspiration []
3 ventilation []
4 oxygen []
5 drugs []
Cried immediately at birth? yes [] no []

2 ONGOING DATA COLLECTION

As per Appendix 6 and 7
After 6 hours = summary of decision on subsequent care.....

3A DATA ON ALL ELIGIBLE INFANTS (DAY THREE)

Outcome
1 Ready for discharge today
2 Ready for discharge, but mother not
3 Well, awaiting weight gain
4 Not well, remains in original allocated cot/incubator or SSC
5 Not well, in high care
6 Not well, in intensive care
7 Died

Cause of death
Date of death
Time of death
Post-mortem?

Type of feeding:

1	breastmilk	[]
2	expressed breastmilk	[]
3	formula	[]
4	mixed	[]

Method of feeding

1	Bottle	[]
2	NG tube	[]
3	Cup/spoon	[]
4	Dropper	[]
5	None / drip	[]

LATCH score

1	Latch	0	1	2
2	Audible swallowing	0	1	2
3	Type of nipple	0	1	2
4	Comfort (breast)	0	1	2
5	Hold (positioning)	0	1	2

Total .....

4B FINAL DATA ON ALL ELIGIBLE INFANTS (DISCHARGE)

Date of discharge
Time of discharge
Weight on discharge

Type of feeding:

1	breastmilk (exclusive)	[]
2	expressed breastmilk	[]
3	formula	[]
4	mixed	[]

Method of feeding

1	Bottle	[]
2	NG tube	[]
3	Cup/spoon	[]
4	Dropper	[]
5	None / drip	[]

Episodes or disease during the study

1	Hypoglycemia	[ ]
2	Hyperthermia	[ ]
3	Hypothermia	[ ]
4	Apnoeas	[ ]
5	Aspiration	[ ]
6	Bacterial infection	[ ]

Specify .....

Complications (diagnoses)
(low birthweight, prematurity, small for gestational age, and other similar categories of neonatal risk are excluded):

1 Main diagnosis: .....
2 Other diagnoses: .....

Episodes of treatment
(write the number of episodes for each treatment category):

Transfer to the conventional system		[ ]
For how many hours/days?		.....
Antibiotic therapy		[ ]
IV fluids		[ ]
Oxygen		[ ]
Rewarming		[ ]
Resuscitation by:		[ ]
1	aspiration	[]
2	mask and bag	[]
3	oxygen	[]
4	intubation	[]
5	sodium bicarbonate	[]
6	ventilation	[]

Outcome

1 Ready for discharge
2 Ready for discharge, but mother not
3 (Well, awaiting weight gain)
4 (Not well, remains in original allocated cot/incubator or SSC)
5 (Not well, in high care)
6 (Not well, in intensive care)
7 Died
Cause of death
Date of death
Time of death
Post-mortem?

Appendix 6
Data collection form first 6 hours
(The table will be expanded so that the "x" will be replaced by the required data)

Data Collection Times in hours and minutes from birth to hour 6

Variable	Hours	0								1				2				3				4				5				6
	Minutes	5	10	15	20	25	30	40	50	0	15	30	45	0	15	30	45	0	15	30	45	0	15	30	45	0	15	30	45	0
Heart rate		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Respiratory rate		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Oxygen saturation		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Apnoea's in period (#)		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Signs of RDS (retraxn, etc)		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Temperature		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Blood sugar (Dx)			x															x												x
Baby behaviour		x	x	x	x	x	x	x	x	x				x				x				x				x				x
Mother behaviour		x	x	x	x	x	x	x	x	x				x				x				x				x				x
Interactions		x	x	x	x	x	x	x	x	x				x				x				x				x				x
Separation time	in period									x				x				x				x				x				x
Breastfeeding										x		x		x				x				x				x				x
Other feeding										x				x				x				x				x				x
Intravenous fluid										x				x				x				x				x				x
Place of care (SSC NICU..)										x				x				x				x				x				x
Room temperature		x								x				x				x				x				x				x
Mother temperature (SSC)		x	x	x	x	x	x	x	x	x				x				x				x				x				x
Incubator temperature		x	x	x	x	x	x	x	x	x				x				x				x				x				x
Nurse time with infant only										x				x				x				x				x				x
Nurse time with mother only										x				x				x				x				x				x
Nurse time with both above										x				x				x				x				x				x

Appendix 7
Data collection form first 3 days
(The table will be expanded so that the "x" will be replaced by the required data)

Data Collection Times in days and hours from hour 6 to day 3

Variable	Days	0											1				2				3
	Hours	0	6	7	8	9	10	11	12	15	18	21	0	6	12	18	0	6	12	18	0
Heart rate		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Respiratory rate		x	x			x			x												
Oxygen saturation		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Apnoea's in period (#)		x	x			x			x												
Signs of RDS (retraction, etc)		x	x			x			x		x		x		x		x		x		x
Temperature		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Blood sugar (Dx)		x	x						x		x		x		x		x		x		x
Baby behaviour		x	x						x		x										
Mother behaviour		x	x						x		x										
Interactions		x	x						x		x										
Time in period spent SSC		x	x						x				x	x	x	x	x	x	x	x	x
Breastfeeding		x	x						x		x		x				x				x
Other feeding		x	x						x		x		x				x				x
Intravenous fluid		x	x						x		x		x				x				x
Feeding details	ongoing												x				x				x
Number of feeds																					
Volume of feeds																					
Place of care (SSC, cot, NICU..)		x	x						x		x		x				x				x
Room temperature		x	x						x		x		x				x				x
Mother temperature (SSC only)		x	x						x		x		x				x				x
Baby weight		x											x				x				x